106TH CONGRESS, 1st Session } HOUSE OF REPRESENTATIVES { REPT. 106–378 Part 1

PAIN RELIEF PROMOTION ACT OF 1999

OCTOBER 13, 1999.—Ordered to be printed

Mr. HYDE, from the Committee on the Judiciary, submitted the following

R E P O R T

together with

DISSENTING VIEWS

[To accompany H.R. 2260]

[Including cost estimate of the Congressional Budget Office]

The Committee on the Judiciary, to whom was referred the bill (H.R. 2260) amending the Controlled Substances Act to promote pain management and palliative care without permitting assisted suicide and euthanasia, and for other purposes, having considered the same, reports favorably thereon without amendment and recommends that the bill do pass.

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79–006

PURPOSE AND SUMMARY

H.R. 2260, the Pain Relief Promotion Act of 1999, was introduced on June 17, 1999, by a bipartisan group of 68 cosponsors and enjoys the support of the American Medical Association and the National Hospice Organization, among many other medical organizations.[1] H.R. 2260 promotes pain management and palliative care through the appropriate use of controlled substances, even if such use unintentionally hastens death, while reinforcing the uniform application of the existing standard that intentionally bringing about the death of any person is not a legitimate use of controlled substances and is not consistent with public health and safety. H.R. 2260 also authorizes the Attorney General to carry out educational training programs for law enforcement personnel and to promote greater understanding of health professionals' legitimate use of controlled substances for pain management, while authorizing the Agency for Health Care Policy and Research in the Department of Health and Human Services to collect and disseminate protocols for palliative care. Finally, H.R. 2260 authorizes a $5,000,000 program under which the Secretary of Health and Human Services may award grants to health professions schools, hospices and other sites to develop and implement palliative care education and training. On June 24, 1999, the subcommittee conducted a hearing on H.R. 2260. On July 20, 1999, the subcommittee passed the bill without amendment by a voice vote. On September 14, 1999, the committee reported the bill favorably without amendment.

BACKGROUND AND NEED FOR THE LEGISLATION

The Controlled Substances Act and the Role of the Drug Enforcement Administration

The Controlled Substances Act of 1970 (CSA) provides a uniform national standard for the control of potentially dangerous drugs, and a system of enforcement and penalties that is, in important respects, independent of State law. The CSA prohibits any distribution of controlled substances unless the distribution is authorized pursuant to a statutory exception.[2] One such exception is distribution pursuant to registration by the Attorney General under 21 U.S.C. § 823. Physicians and pharmacists may apply to the Drug Enforcement Administration (DEA) for a Federal license to prescribe and administer controlled substances. The primary role of

[1] The bill has the express support of some of the leading medical groups in the country such as: American Medical Association, National Hospice Organization, Hospice Association of America, American Academy of Pain Management, American Society of Anesthesiologists, Physicians for Compassionate Care, Christian Medical and Dental Society, Catholic Health Association, Hope Hospice and Palliative Care (Florida), Americans for Integrity in Palliative Care, American College of Osteopathic Family Physicians, Coalition of Concerned Medical Professionals and the Oklahoma State Medical Association. The bill has also been endorsed by the State of Oregon's largest newspaper, the *Oregonian*.

[2] According to 21 U.S.C. § 841, it is "unlawful for any person [to] knowingly or intentionally . . . distribute, or dispense . . . a controlled substance" . . . "[e]xcept as authorized by this subchapter [Control and Enforcement, §§ 801–904]."

DEA with respect to pharmaceutical controlled substances is to prevent, detect, and investigate their diversion from legitimate uses while ensuring their availability for legitimate medical use.[3] While physicians receive their licenses to practice medicine from State medical boards, they receive this separate registration to prescribe controlled substances from the DEA.[4] Prescriptions for these potentially dangerous drugs must be written using DEA registrations on DEA prescription forms.

The CSA was amended in 1984 to strengthen the DEA's ability to prevent diversion of federally regulated prescription drugs for illicit purposes.[5] The chief concern cited as justification for the 1984 amendments was the potential of controlled substances to cause physical harm and death when used for something other than a legitimate medical purpose. According to Representative Hughes, the chief House sponsor of the measure, "The bill gives to DEA greater latitude to suspend or revoke the registration of a practitioner who dispenses drugs in a manner that threatens the public health and safety."[6] The 1984 amendments were designed to give the DEA more independent authority to revoke a physician's registration in cases where a State was unable or unwilling to intervene.[7] The amendments authorized the DEA to revoke a physician's registration where the registration is deemed "inconsistent with the public interest"—in cases where, for example, controlled substances have been misused to endanger "public health and safety."[8]

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[3] All DEA policies, procedures, and investigative programs with respect to this issue are guided by the underlying principle stated in the Code of Federal Regulations which links the validity of any prescription for a controlled substance to the requirement that it be "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04.

[4] As Congress declared in 1984 when it last revised this part of the CSA:

> Registration of a physician under the Controlled Substances Act is a matter entirely separate from a physician's State license to practice medicine. Therefore, revocation of registration only precludes a physician from dispensing substances controlled under the Controlled Substances Act and does not preclude his dispensing other prescription drugs or his continued practice of medicine.

S. Rep. No. 98–225, at 267 (1983), reprinted in 1984 U.S.C.C.A.N. 3182, 3449 n. 40.

[5] The amendments were approved by the U.S. Senate 91–to–1 on February 2, 1984 as part of a Comprehensive Crime Control Act (S. 1762). Almost identical language was approved by the House 392–to–1 on September 18, 1984. The House and Senate versions were reconciled and ultimately approved as part of H.J. Res. 648, a continuing resolution which became law on October 12, 1984 (Pub. L. No. 98–473, 98 Stat. 1987).

[6] 130 Cong. Rec. 25,849 (1984). Representative Hughes also cited a government study indicating that "prescription drugs are responsible for close to 70 percent of the deaths and injuries due to drug abuse." *Id.* at 25,848.

[7] Representative Hamilton Fish, another sponsor of the amendments, said giving such flexibility to the Federal Government was necessary because States often did not respond adequately to these abuses: "State policing of these activities, as well as peer review within the profession, have not been adequate control measures. State laws regarding the dispensing of controlled substances are also inadequate." *Id.* at 25,849.

At a hearing before the House Commerce Subcommittee on Health and the Environment, the DEA called the expanded Federal authority to revoke practitioner registration "one of the most important sections of the bill," not only because States were often ill-equipped to enforce their own drug laws but also because "many controlled drug violations involving prescription drugs are not felonies under State law and therefore cannot be used in a DEA revocation action" under then-existing law. *Dangerous Drug Diversion Control Act of 1984: Hearing on H.R. 5656 Before the Subcomm. On Health and the Env't of the House Comm. On Energy and Commerce*, 98th Cong. 404 (1984) (statement of Gene R. Haislip, Deputy Assistant Administrator, Drug Enforcement Administration).

[8] As Representative Charles Rangel said in support of the amendments:

> Under current law, the DEA must register physicians, pharmacies, or other practitioners if they are authorized to dispense drugs by the law of the State in which they practice. . . . The public interest standard added by H.R. 5656 will provide greater flexibility to deny or revoke registrations in the most egregious cases.

Continued

21 U.S.C. § 823 of the CSA sets forth registration requirements for controlled substances licenses and § 824 sets forth grounds for revocation. Physicians who abuse their registrations and prescribe controlled substances for non-medical purposes are subject to license revocation under § 824 and to potential criminal prosecution under § 841.[9] Section 823 provides that the Attorney General may deny an application for registration "if such registration would be inconsistent with the public interest" as determined by consideration of several factors.[10]

Two of the factors listed under § 823 that are relevant to assisted suicide are: compliance with State law relating to controlled substances (21 U.S.C. § 823 (f)(4)), and the public health and safety (21 U.S.C. § 823 (f)(5)). Most States specifically prohibit assisted suicide; no State has authorized assisted suicide except Oregon.[11] Public health and safety has been invoked as separate grounds for revoking the registrations of physicians who prescribe drugs used in lethal overdoses.[12] In some cases, the physicians were found to

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130 Cong. Rec. 25,852 (1984).

[9] In practice, a criminal proceeding is almost never initiated. Instead, an administrative penalty is applied (simply revoking or suspending the physician's special Federal privilege to handle controlled substances), and this effectively prevents further illicit use. Typically, the DEA does not initiate action at all until after the State has acted against a registrant.

[10] 21 U.S.C. § 824(a)(4) provides that one of the grounds for revocation is the commission of "such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section."

[11] Currently, 44 States prohibit assisted suicide, either through statutes or common law. Thirty-eight States prohibit assisted suicide through statutes: Alaska (Act 97–187; 1997 Session Laws), Arizona (Ariz. Rev. Stat. Ann., § 13–1103(A)(3) (West Supp. 1996–1997)), Arkansas (Ark. Code Ann., § 5–10–104(a)(2) (1993)), California (Cal. Penal Code, § 401 (West 1988)), Colorado (Colo. Rev. Stat. § 18–3–104(1)(6) (Supp. 1996)), Connecticut (Conn. Gen. Stat. § 53a–56(a)(2) (1997)), Delaware (Del. Code Ann., tit. 11, § 645 (1995)), Florida (Fla. Stat. § 782.08 (West 1992)), Georgia (Ga. Code Ann., § 16–5–5(b) (1996)), Hawaii (Haw. Rev. Stat. § 707–702(1)(6) 1993)), Illinois (Ill. Comp. Stat., ch. 720, § 5/12–31(a)(2) (Smith-Hurd Supp. 1996)), Indiana (Ind. Stat. Ann., §§ 35–42–1–2 to 35–42–1–2.5 (1994 and Supp. 1996)), Iowa (Iowa Code Ann. §§ 707A.2, 707A.3 (Supp. 1997)), Kansas (Kan. Stat. Ann., § 21–3406 (1995)), Kentucky (Ky. Rev. Stat. Ann., § 216.302 (Michie 1994), Louisiana (La. Rev. Stat. Ann., § 14:32.12 (West Supp. 1997)), Maine (Me. Rev. Stat. Ann., tit. 17–A, § 204 (West 1983)), Maryland (1999 Md. Laws 700), Michigan (Mich. Comp. Laws Ann., §752.1027 (West Supp. 1997–1998)), Minnesota (Minn. Stat. Ann., § 609.215 (West 1987 and Supp. 1996)), Mississippi (Miss. Code Ann., § 97–3–49 (1994)), Missouri (Mo. Ann. Stat., § 565.023(1)(2) (West Supp. 1996)), Montana (Mont. Code Ann., § 45–5–105 (1995)), Nebraska (Neb. Rev. Stat. Ann., § 28–307 (Michie 1995)), New Hampshire (N.H. Rev. Stat. Ann., § 630:4 (1996)), New Jersey (N.J. Stat. Ann., § 2C:11–6 (West 1995)), New Mexico (N.M. Stat. Ann., § 30–2–4 (Michie 1994)), New York (N.Y. Penal Law, §§ 120.30, 125.15(3) (McKenney, 1987)), North Dakota (N.D. Cent. Code, § 12.1–16–04 (Supp. 1995)), Oklahoma (Okla. Stat. Ann., tit. 21, §§ 813, 814, 815 (West 1983)), Pennsylvania (Pa. Cons. Stat. Ann., tit. 18, § 2505(b) (West 1983)), Rhode Island (R.I. Gen. Laws §§ 11–60–1 through 11–60–8 (Supp. 1996)), South Carolina (S.C. Code Ann., §16–3–1090 (1998)), South Dakota (S.D. Certified Laws Ann., §22–16–37 (Michie 1988)), Tennessee (Tenn. Code Ann., § 39–13–216 (Supp. 1995)), Texas (Tex. Penal Code Ann., § 22.08 (West 1994)), Virginia (Va. Code Ann., § 8.01–622.1 (Michie 1999)), Washington (Wash. Rev. Code Ann., § 9A.36.060 (West 1988)), Wisconsin (Wis. Stat. Ann., § 940.12 (West 1996)). Six States criminalize assisted suicide through common law: Alabama, Idaho, Massachusetts, Nevada, Vermont, and West Virginia. Issue Brief, Health Policy Tracking Service, National Conference of State Legislature, (Sept. 17, 1999) (Maria Rothoner and Elizabeth Kaiser).

[12] See, e.g., Denial of Registration of Dr. Samuel Fertig, 49 Fed. Reg. 6577 (Feb. 22, 1984) (denied a registration for prescribing massive quantities of controlled substances to several young people who used them in lethal overdoses, despite fact that state license had been restored, on grounds that he "was responsible, directly or indirectly, for the deaths of several young people"); Revocation of Registration of Dr. Murray Walker, 55 Fed. Reg. 5306 (Feb. 14, 1990) (registration revoked for prescribing Percodan for non-medical purposes to several people, one of whom died of an overdose, the DEA stating, "Substances are controlled because they are potentially dangerous and therefore should be handled with extreme care. Respondent has failed to exercise such care and, as a result, has ignored his duties as a health care professional to protect the public health and safety from the illicit use of these drugs.") See 21 U.S.C. § 824(c) for the procedure for such a suspension or revocation, and 21 U.S.C. § 824(d) for the authority to "suspend any registration simultaneously with the institution of proceedings under this section, in cases where [the Attorney General] finds that there is an imminent danger to the public health or safety."

have been negligently involved in suicides or attempted suicides.[13] Each of these cases was theoretically a candidate for criminal prosecution under § 841, but, apparently, no federal criminal prosecution followed. Even where physicians were previously convicted of manslaughter under State law for negligent and reckless involvement in a suicide or other lethal overdose, the separate Federal standard of "public health and safety" was the basis upon which the registration was revoked and, in one case, reinstatement repeatedly denied.[14]

Chronology of Events Preceding H.R. 2260

On November 8, 1994, Oregon voters approved Ballot Measure 16, legalizing physician-assisted suicide, by a margin of 51% to 49%.[15] On November 27, 1994, however, a lawsuit was filed against the Death with Dignity Act on equal protection and due process grounds.[16] On August 3, 1995, the law was held unconstitutional as a violation of the Equal Protection Clause. The State appealed the decision, and on February 27, 1997, the Ninth Circuit overturned the ruling on the basis of the plaintiffs' lack of standing.[17] On October 27, 1997, the Ninth Circuit lifted the injunction against the Act. On November 4, 1997, Oregon voters rejected a referendum asking for the repeal of the Act[18] and the measure was implemented at that time.

During the litigation over Oregon's assisted suicide law, Congress debated the issue of Federal funding for assisted suicide. On April 30, 1997, after a vote of 398–16 in the House and a unani-

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[13] See, e.g., Denial of Registration of Dr. Pompeyo Q. Braga Bonado, 55 Fed. Reg. 37579 (Sept. 12, 1990). Here, the DEA found that granting a registration to this physician would be "clearly contrary to the public interest." *Id.* at 37580. The physician had prescribed controlled substances to several individuals "for no legitimate medical purpose," including to one man addicted to Percocet who was hospitalized after a suicide attempt. "As a health care professional and DEA registrant," the DEA stated, "Respondent bears a heavy responsibility to ensure that the controlled substances he prescribes are not abused." *Id.* at 37580.

[14] In the case of Revocation of Registration of Hugh Schade, M.D., 60 Fed. Reg. 56354 (Nov. 8, 1995). Dr. Schade gave potentially lethal amounts of Darvocet to a depressed patient who used them to commit suicide. Giving these drugs to a patient in this mental state, said one expert witness, was "like handing him a loaded gun." While Dr. Schade was also convicted of negligent homicide under state law because of this case, his DEA application was denied not on the basis that he had violated a state law, but on the separate basis that his conduct objectively threatened "public health and safety".

In the case of Revocation of Registration of David W. Bradway, M.D., 48 Fed. Reg. 49937 (Oct. 28, 1983), the physician's registration was revoked after conviction under state law on various counts, most notably "one count of manslaughter by unlawfully distributing controlled substances in such a grossly negligent [and] reckless manner as to cause the death of an individual" *Id.* at 49937. Years later, after allegedly rehabilitating and resuming medical practice, the physician applied for a new DEA registration; citing the fact that "a death was directly attributable to Respondent's misuse of his DEA Certificate of Registration," the DEA denied the application, stating: "It is the position of the DEA that a Certificate of Registration to handle controlled substances is a privilege, not a right, and it should only be granted to doctors who have demonstrated high standards of ethical conduct and who are completely trustworthy in handling dangerous controlled substances which, as can be seen in this case, can have a devastating impact on individuals who abuse them." 54 Fed. Reg. at 53384. In 1992 he again applied for a DEA registration, but due to "the egregious nature of Respondent's past conduct," the DEA ruled in 1994 (15 years after the patient's death) that "the registration of the Respondent is still not in the public interest". *Id.* at 6299.

[15] See Spencer Heinz, *Assisted Suicide: Advocates Weigh In*, Oregonian, Dec. 9, 1994, at A1.

[16] See *Lee* v. *Oregon*, 891 F. Supp. 1429, 1431 (D. Or. 1995). Federal District Court Judge Michael Hogan agreed with the opponents and issued a temporary restraining order against implementation of the Act on the day before it was to go into effect, pending a full hearing of their claims. On December 27, 1994, Judge Hogan replaced his temporary restraining order with a preliminary injunction, further delaying implementation of the Act.

[17] On May 16,1997, a petition for writ of certiorari was filed with the United States Supreme Court, and the Court denied the petition on October 14, 1997.

[18] The referendum failed by a vote of 60% to 40%.

mous vote in the Senate, the President signed the Assisted Suicide Funding Restriction Act of 1997,[19] which prohibits the use of Federal funds to cause a patient's death. The Act effectively prohibits the practice of assisted suicide in Federal health facilities, removes it from the scope of "treatments" on which patients must be informed under the Federal Patient Self-Determination Act, and forbids Federal subsidies to health programs or benefit packages which include assisted suicide. President Clinton lauded the bill, saying it "will allow the Federal Government to speak with a clear voice in opposing these practices," and warning that "to endorse assisted suicide would set us on a disturbing and perhaps dangerous path."[20]

Also in 1997, the Supreme Court reviewed two Circuit Court of Appeal rulings regarding the assisted suicide laws of New York and Washington, and concluded that laws prohibiting assisted suicide do not violate the U.S. Constitution. The Solicitor General of the United States filed briefs as *amicus curiae* opposing the overturning of the State laws in each case.[21] In his brief in the *Glucksberg* case, the Solicitor General asserted that there is a clear ethical and legal distinction between pain control that unintention-

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[19] 42 U.S.C. § 14401.

[20] Statement by President William Jefferson Clinton Upon Signing H.R. 1003, 33 Weekly Comp. Pres. Doc. 617 (May 5, 1997).

[21] Brief for the United States as Amicus Curiae Supporting Petitioners at 17–18, *Washington* v. *Glucksberg*, 521 U.S. 702 (1997) (No. 96–110). Relevant portions of the *Glucksberg* brief are as follows: Health facilities controlled by the Federal Government "do not permit physicians to assist patients in committing suicide by providing lethal dosages of medication." *Id.* at 1; "Overriding State interests justify the State's decision to ban physicians from prescribing lethal medication." *Id.* at 9; "There is an important and common-sense distinction between withdrawing artificial supports so that a disease will progress to its inevitable end, and providing chemicals to be used to kill someone." *Id.*; "Once a State decides to create an exception to its prohibition against assisted suicide, there is no obvious stopping point." *Id.* at 10; "One special source of concern is that terminally ill persons who contemplate suicide often suffer from undiagnosed depression and inadequately treated pain . . . In most cases, once appropriate treatment is provided, the desire for suicide abates." *Id.* at 19; "Any exception to the ban on assisted suicide therefore runs a very significant risk that persons with treatable depression and pain will be allowed to commit suicide. A State has an overriding interest in avoiding that risk and in protecting persons who would want to remain alive if provided with the appropriate treatment." *Id.* at 20; "Another area of concern is that terminally ill patients are often extremely vulnerable and susceptible to influence by physicians, family members, and others on whom they depend for support... The point is not that physicians or family members will attempt to coerce persons into committing suicide, although there may be some cases of that. The real dangers are much more subtle and extremely difficult to monitor and address." *Id.*; "Another difficulty with permitting doctors to prescribe lethal drugs for terminally ill patients is that illnesses can be misdiagnosed as terminal . . . If the State were to create an exception to its ban on assisted suicide for terminally ill adults, such a misdiagnosis could have tragic consequences . . . The State has an overwhelmingly strong interest in preventing such tragedies from occurring." *Id.* at 22; In the Netherlands, which allowed assisted suicide with safeguards, "a recent study shows that those procedural safeguards have not worked." *Id.* at 23; "[T]here is a very significant distinction between removing artificial supports—and thereby allowing the underlying disease to progress to its inevitable end—and providing chemicals to kill someone. In one case, the cause of death can reasonably be viewed as the underlying disease; in the other, the cause of death can only be viewed as the lethal medication." *Id.* at 24; "Once a legislature abandons a categorical prohibition against physician assisted suicide, there is no obvious stopping point." *Id.* at 26.

Similarly, after reviewing various Federal policies that forbid physician assisted suicide (as defined above) in VA hospitals, military hospitals, NIH, and Indian Health Service, the Solicitor General's *amicus* brief in *Vacco* v. *Quill* stated: "No Federal law authorizes or encourages physician assisted suicide." Brief for the United States as Amicus Curiae Supporting Petitioners at 2, *Vacco* v. *Quill*, 521 U.S. 793 (1997) (No. 95–1858); "To let a patient die is to acknowledge the futility of further medical treatment and to let nature run its course . . . Physician prescribed lethal medication, in contrast, provides its own fatal pathology." *Id.* at 10; "The medical profession recognizes ethical distinctions between discontinuing unwanted, futile treatments and using the tools of medicine to cause a patient's death." *Id.* at 11 (citing the AMA); "With the provision of lethal medication, the physician provides the cause of the patient's death." *Id.* at 12.

ally hastens death and the prescribing of lethal drugs with the intent to cause death:

> [T]he ethical standards of the medical community have long permitted physicians to prescribe medication in sufficient doses to relieve pain, even when the necessary dose will hasten death . . . So long as the physician's intent is to relieve pain, and not to cause death, such treatment does not violate the ethical standards of the medical community.[22]

Importantly, the Solicitor General also asserted that "no Federal law . . . either authorizes or accommodates physician assisted suicide."[23]

After Oregon's law was enacted, Judiciary Committee Chairman Henry J. Hyde inquired of the Administrator of the DEA, Thomas K. Constantine, whether Oregon's new law would have any impact on the administration of the CSA. Administrator Constantine replied on November 5, 1997, declaring physician assisted suicide with the use of federally controlled substances to be inconsistent with the CSA.[24] Under the DEA ruling, doctors given a Federal license under the CSA to prescribe federally controlled substances could not prescribe them for the purpose of assisting in a suicide. Constantine agreed with the sentiment of many members of Congress that administering a drug to deliberately cause someone to die is not a "legitimate medical purpose" within the meaning of the Controlled Substances Act.[25]

On June 5, 1998, however, the Attorney General of the United States ruled that administering controlled substances for the purpose of causing death is to be considered part of the ordinary practice of medicine in Oregon and, therefore, exempt from CSA and DEA jurisdiction. Under the Attorney General's ruling, the CSA is enforceable against the use of controlled substances for assisted suicide in Oregon only to the extent that physicians do not comply with the provisions of Oregon's law.[26] Under Attorney General Reno's ruling, a DEA registration cannot be denied, revoked, or suspended in the case of "a physician who has assisted in a suicide in compliance with Oregon law."[27] "Adverse action against a physician who has assisted in a suicide in full compliance with the Or-

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[22] *Glucksberg,* 521 U.S. at 17

[23] Solicitor General's Amicus Brief at 2, *Glucksberg* (No. 96–110).

[24] Letter from The Honorable Thomas K. Constantine, Administrator of the Drug Enforcement Administration of the United States, to Chairman Henry J. Hyde, Committee on the Judiciary, U.S. House of Representatives (Nov. 5, 1997).

[25] Administrator Constantine concluded in his letter to Chairman Hyde that, "delivering, dispensing, or prescribing a controlled substance with the intent of assisting a suicide would not be under any current definition a legitimate medical purpose." *Id.*

[26] In her letter to Chairman Hyde, however, Attorney General Janet Reno failed to mention the existing regulatory requirement that practitioners prescribe federally controlled substances only for a "legitimate medical purpose":

> The CSA is a complex regulatory scheme that controls the authorized distribution of scheduled drugs. Physicians, for example, are authorized to prescribe and distribute scheduled drugs only pursuant to their registration with the DEA, and the unauthorized distribution of drugs is generally subject to criminal and administrative action. The relevant provisions of the CSA provide criminal penalties for physicians who dispense controlled substances beyond "the course of professional practice," 21 U.S.C. § 802(21), see *Id.* § 841(b), and provide for revocation of the DEA drug registrations of physicians who have engaged either in such criminal conduct or in other "conduct which may threaten the public health and safety." *Id.* § 823(f).

Letter from The Honorable Janet Reno, Attorney General of the United States, to Chairman Henry J. Hyde, Committee on the Judiciary, U.S. House of Representatives (June 5, 1998).

[27] *Id.*

egon Act would not be authorized by the CSA."[28] DEA investigation would therefore focus not on whether controlled substances have been used to take human life, but on whether human life has been destroyed in conformance with Oregon law. The Attorney General's ruling commits the DEA to a role to which it has never been assigned under the CSA—that of regulating assisted suicide as a "legitimate medical practice." This is a sharp departure from the intended purposes of the Controlled Substances Act, and from the policy required in all other Federal programs under the Assisted Suicide Funding Restriction Act.

Congressmen Henry Hyde and James Oberstar introduced a bill on June 5, 1998, in the 105th Congress, to address the problems created by the Attorney General's ruling. That bill, H.R. 4006, was reported out of committee but no further action was taken. H.R. 2260 was introduced in the 106th Congress on June 17, 1999 by Congressmen Henry Hyde and Bart Stupak.

Oregon's Assisted Suicide Law

On February 17, 1999, the Oregon Health Division released a report detailing the first full year under Oregon's physician-assisted suicide law. Twenty-three individuals received lethal substances in 1998 pursuant to the Act, while fifteen actually used the substances to cause their deaths.[30] Thirteen had cancer, one had a chronic lung condition and one had congestive heart failure. Only fourteen had lived in Oregon for at least six months.

The report is lacking in several respects. It does not provide objective information about the extent to which physicians have complied with the law, but, instead, relies heavily on physician self-reporting. This deficiency in objective reporting is exacerbated by the fact that the law itself is governed by a "good faith" standard that protects physicians from civil, professional, and criminal liability so long as they believe "in good faith" that they have complied with the guidelines.[31] The report makes no serious effort to uncover the extent of covert assisted-suicide,[32] and the law's confidentiality requirements[33] and its provision barring notification of family mem-

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[28] *Id.*

[30] Of these fifteen, eight were men and seven were women. Of the eight who did not use the medication, six died from their own illnesses before taking the drugs and two were alive as of January 1, 1999.

[31] Or. Rev. Stat. § 127.885 (1997). The governor of Oregon has testified that he knows of no State penalties for violating the State guidelines. *Lethal Drug Abuse Prevention Act: Hearing on H.R. 4006 Before the Subcomm. on the Constitution of the House Comm. on the Judiciary*, 105th Cong. (July 14, 1998) (oral statement of Gov. John Kitzhaber). An Oregon physician generally acknowledged to have performed active euthanasia without his patient's consent (still a homicide under Oregon law) was declared "unprosecutable" by State officials because of the climate created by the Oregon law permitting assisted suicide. See *Doctor won't be prosecuted*, The Bulletin (Bend, OR), Dec. 11, 1997, at 7.

[32] Upon releasing the report, the Oregon Health Division distributed a memorandum to State employees stating that any employee who reveals that a physician-assisted death has occurred in his or her county "will immediately be terminated." Death with Dignity Memorandum from Sharon Rice, Manager Registration Unit, Center for Health Statistics of the Oregon Health Division, to County Vital Records Registrars and Deputies (Dec. 12, 1997) *reprinted* in Confidentiality of Death Certificates, 14 Issues in Law & Med. 333, 334 (1998). This memorandum indicates that the real purpose of this report might have been something other than the discovery and disclosure of all relevant information.

[33] Or. Rev. Stat. § 127.865 (1997).

bers without a patient's express consent[34] make it very unlikely that abuses will be discovered.[35]

Significantly, the report fails to provide any meaningful information on the mental state of the patients. Under the Oregon law, physicians are to assist suicides only in cases where a patient is expected to die in six months,[36] yet physicians generally concede, and the professional literature confirms, that such predictions of life expectancy are unreliable.[37] In addition, physicians are to assist suicides only in cases where a patient is *not* suffering from "a psychiatric or psychological disorder, or depression causing impaired judgment."[38] Most physicians are ill-equipped to detect depression in their patients at all, much less to determine what level of clinical depression is sufficient to cause "impaired judgment."[39]

Specific omissions highlight the untrustworthiness of the report. The report fails to mention that the first publicly-reported case of assisted suicide in the State involved an out-of-State woman who was found to be depressed by one doctor she consulted. Within three weeks of contacting Compassion in Dying and moving to Oregon, she was dead by lethal overdose. Significantly, while two doctors had rendered opinions against the assisted suicide, including a physician who believed the woman was suffering from clinical depression, these opinions were not included in the report.[40]

The Pain Relief Promotion Act of 1999

Palliative Care is a Legitimate Medical Purpose for Controlled Substances

In Title I, The Pain Relief Promotion Act amends the CSA to expressly permit and encourage the use of controlled substances for pain management and palliative care, even where such use might

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[34] Or. Rev. Stat. § 127.835 (1997).

[35] Another factor worthy of note is that, during the first year of the assisted suicide law's operation, the Oregon Health Plan placed barriers to the funding of antidepressants (Jeanette Hamby, *The Enemy Within: State Bureaucratic Rules Threaten the Spirit of Oregon Health Plan's Founding Principles*, Oregonian, Jan. 21, 1998), restricted the availability of mental health services (Joe Rojas-Burke, *Survey Gives Oregon Health Plan High Marks*, Oregonian, Feb. 3, 1999, at B15), and restricted pain medication for poor and disabled patients (Diane Gianelli, *Suicide Opponents Rip Oregon Medicaid Pain Control Policy*, American Medical News, Sept. 28, 1998). By contrast, Oregon fully funds assisted suicide. See *Pain Relief Promotion Act of 1999, Hearing on H.R. 2260 Before the Subcomm. on the Constitution of the House Comm. on the Judiciary*, 106th Cong. (June 24, 1999) (statement of N. Gregory Hamilton, M.D., President of Physicians for Compassionate Care) <<http://www.house.gov/judiciary/hami0624.htm>> [hereinafter cited as Hamilton Testimony]. Some private Health Maintenance Organizations have begun to place caps on in-home palliative care while fully funding assisted suicide. *Id.*

[36] Or. Rev. Stat. § 127.800, 127.805 (1997).

[37] Joanne Lynn et al., *Defining the "Terminally Ill": Insights from SUPPORT*, 35 Duquesne Law Review 311 (1996); Eric Chevlen, *The Limits of Prognostication*, 35 Duquesne Law Review 337 (1996); R.A. Pearlman, *Inaccurate Predictions of Life Expectancy*, 148 Archives of Internal Medicine 2537 (1988).

[38] Or. Rev. Stat. § 127.825 (1997).

[39] *Lethal Drug Abuse Prevention Act: Hearing on H.R. 4006 before the Subcomm. on the Constitution of the House Comm. on the Judiciary*, 105th Cong., 2d Sess. (July 14, 1998) (oral statement of Dr. Herbert Hendin). See also, *When Death is Sought: Assisted Suicide and Euthanasia in the Medical Context*, New York State Task Force on Life and the Law (May 1994), 126–8. The chief author of the Oregon law has written somewhat chillingly that "depression in itself does not rule out the physician's assistance" under the Act. See Cheryl K. Smith, *Safeguards for Physician-assisted Suicide: The Oregon Death with Dignity Act, in Death, Dying and the Law* 75 (S. McLean ed., 1996).

[40] See Herbert Hendin *et al., Physician-Assisted Suicide: Reflections on Oregon's First Case*, 14 Issues in Law & Med. 243 (1998).

unintentionally hasten death.[41] H.R. 2260 would include in the CSA for the first time an endorsement of pain control as a "legitimate medical purpose" for the use of controlled substances. Until now, such affirmations have been relegated to documents, such as physicians' manuals, which do not have the force of law.

Section 303(i)(1) of the CSA as amended by H.R. 2260 would read:

> For purposes of this Act and any regulations to implement this Act, alleviating pain or discomfort in the usual course of professional practice is a legitimate medical purpose for the dispensing, distributing, or administering of a controlled substance that is consistent with public health and safety, even if the use of such a substance may increase the risk of death.

This text makes clear that practitioners may legally dispense controlled substances to alleviate pain and discomfort. By defining the alleviation of pain or discomfort as a legitimate medical purpose, H.R. 2260 protects practitioners from undue scrutiny or suspicion when they exercise their professional judgment in determining how most effectively to relieve pain. H.R. 2260 further reaffirms that the CSA does not authorize the use of controlled substances for assisting suicide. Section 303(i)(1) of the CSA as amended would read: "Nothing in this section authorizes intentionally dispensing, distributing, or administering a controlled substance for the purpose of causing death or assisting another person in causing death."

H.R. 2260 thus codifies what is sometimes called the "principle of double effect" with regard to the use of federally controlled substances.[42] The distinction between intended and unintended has-

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[41] Because the language of H.R. 2260 applies only to *dispensing, distributing, or administering* controlled substances, it can only apply to schedule II, III, IV, or V drugs. Schedule I drugs, such as marihuana (21 C.F.R. section 1308.11(d)(19)), may not be dispensed for any reason but may be used only for approved research. 21 U.S.C. section 823(f) provides, "The Attorney General shall register practitioners (including pharmacies, as distinguished from pharmacists) to dispense, or conduct research with, controlled substances in schedule II, III, IV, or V, if the applicant is authorized to dispense, or conduct research with respect to, controlled substances under the laws of the State in which he practices. The Attorney General may deny an application for such registration if he determines that the issuance of such registration would be inconsistent with the public interest. In determining the public interest, the following factors shall be considered: . . . (5) such other factors as may be relevant to and consistent with the public health and safety." By contrast, the only provision authorizing registration of practitioners with respect to schedule I controlled substances is for research: "Registration applications by practitioners wishing to conduct research with controlled substances in schedule I shall be referred to the Secretary, who shall determine qualifications and competency of each practitioner requesting registration." *Id.* Thus, a physician's or pharmacist's registration to dispense controlled substances under 21 U.S.C. section 823 does not apply to or authorize dispensing marihuana since it is a schedule I controlled substance.

[42] The subcommittee heard testimony from a doctor specializing in hospice care who described actions intended to cause death and contrasted them with the way in which controlled substances were used to attempt to ease the pain of an AIDS patient where death was unintended. Causing a patient's death requires a sudden massive overdose of potentially dangerous drugs. Pain control involves carefully adjusting dosage until it achieves relief of pain with a minimum of side-effects. This gradual adjustment of dosage is exactly what must be avoided if one's intent is to kill—because patients quickly build up a resistance to side-effects such as the suppression of breathing. See *Pain Relief Promotion Act of 1999: Hearing on H.R. 2260 Before the Subcomm. on the Constitution of the House Comm. on the Judiciary*, 106th Cong. 2 (June 24, 1999) (statement of Walter R. Hunter, M.D., VistaCare Hospice) <<http://www.house.gov/judiciary/hunt0624.htm>> [hereinafter cited as Hunter Testimony].

According to Dr. Walter Hunter:

> On a Monday morning the hospice for whom I worked received a phone call from his family that he was having difficulty breathing. His nurse and I made a house call. When we entered the room we could hear his laborious and moist respirations across the room. His respiratory rate was 44 and he was unconscious. We immediately set to

tening of death enjoys broad support in codes of medical ethics as well as in the Assisted Suicide Funding Restriction Act of 1997.[43] Many States have passed laws banning assisted suicide, including provisions specifically emphasizing the distinction between assisted suicide and unintentional hastening of death in the course of pain control. In upholding New York's law against assisted suicide, the U.S. Supreme Court noted:

> [w]hen a doctor provides aggressive palliative care . . . painkilling drugs may hasten a patient's death, but the physician's purpose and intent is, or may be, only to ease his patient's pain. A doctor who assists a suicide, however, "must, necessarily and indubitably, intend primarily that the patient be made dead." [Assisted Suicide in the United States, Hearing before the Subcomm. on the Constitution of the House Comm. on the Judiciary, 104th Cong., 2d Sess., 367 (1996) (testimony of Dr. Leon R. Kass)].[44]

Title I, Section 303(i)(2) of the CSA as amended by H.R. 2260 would ensure the uniform application of the CSA in every jurisdiction: "Notwithstanding any other provision of this Act, in determining whether a registration is consistent with the public interest under this Act, the Attorney General shall give no force and effect to State law authorizing or permitting assisted suicide or euthanasia." If H.R. 2260 were to be enacted, using controlled substances to cause death will be regarded as inconsistent with public health and safety in all 50 States, as it had been prior to the Attorney General's 1998 ruling.[45]

Enforcement of Title I Provisions

H.R. 2260 distinguishes between the use of controlled substances with the intent to manage pain and the use of controlled substances with the intent to cause death. This distinction does not

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> work. I gave him 40 mg of Lasix (furosemide) intravenously. There was no effect. I then gave him 10 mg of morphine intravenously. There was no effect after several minutes. I repeated the dose of 10 mg of morphine and waited several minutes. Again, there was no effect. I gave 5 mg of morphine. There was still no effect. I then gave 5 mg of Valium (diazepam) in an attempt to sedate him and ease the work of breathing. There was no effect. I repeated the Valium dose and there was still no effect. I gave 5 mg of morphine, waited, saw no effect and gave another 10 mg of morphine. After a few minutes, his respirations decreased to about 20. This was a reasonable goal. However, instead of stabilizing at 20, they continued to diminish and he stopped breathing several minutes later.

Id. Dr. Hunter also testified repeatedly that H.R. 2260 would not change the way he practices palliative care. Hunter Testimony.

[43] 42 U.S.C. § 14402(b)(4). In distinguishing palliative care from euthanasia, the subcommittee heard testimony that:

> [t]he medical profession has long recognized that efforts to control pain using powerful drugs may sometimes have side-effects . . . The physician's intent in these cases, however, is to use the minimum dosage needed to control the pain; any risk of hastening death is not intended, but is foreseen as the unavoidable side-effect of a legitimate medical action.

See *Pain Relief Promotion Act of 1999: Hearing on H.R. 2260 Before the Subcomm. on the Constitution of the House Comm. on the Judiciary*, 106th Cong. 3–4 (June 24, 1999) (statement of Richard M. Doerflinger, National Conference of Catholic Bishops) <<http://www.house.gov/judiciary/doer0624.htm>> [hereinafter cited as Doerflinger Testimony]. "The important factor here is the agent's intent . . . The goal of pain control is a patient who is relieved of pain. The goal of assisted suicide is a world that is relieved of one more patient." *Id.* at 4.

[44] *Vacco* v. *Quill*, 117 S.Ct. 2293, 2298–9, 2302 (1997).

[45] Importantly, H.R. 2260 does not preempt Oregon's law legalizing assisted suicide in specified circumstances. Its only legal effect is to forbid the use of those drugs which are federally controlled for this purpose.

create a new requirement that law enforcement officials question doctors' intent in using controlled substances for pain control. The Federal Assisted Suicide Funding Restriction Act, which governs all Federal health programs and health facilities, uses this same distinction between pain control that may unintentionally hasten death and the intentional use of drugs to assist suicides. In addition, the overwhelming majority of State laws prohibiting assisted suicide use the *scienter* requirement of "intent" to determine whether a physician has violated the criminal law by providing potentially lethal drugs to a patient.[46] Moreover, since § 823(f)(4) of the CSA regards noncompliance with State law as one factor for consideration in the denial or revocation of a controlled substances registration, the concept of intentional assistance in suicide was routinely contemplated in the enforcement of the CSA prior to H.R. 2260.

It is the committee's view that, while the States are the first line of defense against misuse of prescription drugs, the Federal Government should enforce its own standard as to what constitutes such misuses when a State cannot or will not do so. In Oregon, reports and records required by the assisted suicide law will demonstrate whether federally controlled substances have been intentionally dispensed to assist suicide. Under section 127.865(b) of the Oregon Revised Statutes, "The [Oregon Health] Division shall require any health care provider upon dispensing medication pursuant to ORS 127.800 to 127.897 to file a copy of the dispensing

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[46] *E.g.*, Louisiana (La. Rev. Stat. Ann. § 32.12 (West 1998)) in 1995; Rhode Island (R.I. Gen. Laws. § 11–60–3 (1998)) and Iowa (Iowa Code Ann. § 707A.2 (West 1998) in1996; Virginia (Va. Code Ann. § 8.01–622.1 (Michie 1999)) in 1998, and Maryland (1999 Md. Laws 700) in 1999.

Various State laws use the following phrases: "intentionally causes or aids another person to commit suicide" N.Y. Penal Law § 125.15 (McKinney 1999), Conn. Gen. Stat. Ann. § 53a–56 (West 1999), and Or. Rev. Stat. § 163.125 (1998); "purposely aids another to commit suicide", N.J. Stat. Ann. § 2C:11–6 (West 1999) ; "purposely causes or aids another person to commit suicide" Ark. Code. Ann. § 5–10–104 (Michie 1997); "intentionally aids or solicits another to commit suicide" 18 Pa. Cons. Stat. Ann. § 2505 (West 1998); "purposely aids or solicits another to commit suicide" N.H. Rev. Stat. Ann. § 630:4 (1998); "intentionally in any manner advises, encourages, abets or assists another in taking his own life" S.D. Codified Laws § 22–16–37 (Michie 1999); "willfully furnishes another person with any deadly weapon or poisonous drug, knowing that such person intends to use such weapon or drug in taking his own life . . . , if such person thereafter employs such instrument or drug in taking his own life" Okla. Stat. Ann. tit. 21, § 814 (West 1998); "deliberately aiding another in the taking of his own life" N.M. Stat. Ann. § 30–2–4 (Michie 1999); "intentionally aids another person to commit suicide" Alaska Stat. § 11.41.120 (Michie 1998), Del. Code Ann. tit. 11, § 632 (1998); "deliberately aids, or advises, or encourages another to commit suicide" Cal. Penal Code § 401 (West 1998); "intentionally or knowingly aids, abets, facilitates, solicits, or incites another person to commit suicide," or "provides to, delivers to, procures for, or prescribes for another person any drug or instrument with knowledge that the other person intends to commit suicide with the drug or instrument" N.D. Cent. Code § 12.1–16–04 (1999); "with the purpose of assisting another person to commit or to attempt to commit suicide, knowingly and intentionally either: (1) provides the physical means by which another person commits or attempts to commit suicide, or (2) participates in a physical act by which another person commits or attempts to commit suicide" Ky. Rev. Stat. Ann. § 216.302 (Michie 1998).

Some States have explicit disclaimers about pain control; for example: "This section does not apply to the following: (1) A licensed health care provider who administers, prescribes, or dispenses medications or procedures to relieve a person's pain or discomfort, even if the medication or procedure may hasten or increase the risk of death, unless such medications or procedures are intended to cause death." Ind. Code Ann. § 35–42–1–2.5 (1999); "health care professional," and "unless the medications or procedures are knowingly and intentionally administered, prescribed, or dispensed to cause death." Ky. Rev. Stat. Ann. § 216.304 (1998); "[assisted suicide prohibitions] do not preclude the use of medications or procedures necessary to relieve a person's pain or discomfort if the use of the medications or procedures is not intentionally or knowingly prescribed or administered to cause the death of that person." N.D. Cent. Code § 12.1–16–06 (1999).

Even Oregon's criminal law continues to punish actions in which a person intentionally causes or aids another person in committing suicide except for a certain class of terminally ill people. Or. Stat. § 163.125 (1999).

record with the division." Thus, in order to escape criminal liability that would otherwise exist under Oregon law for assisting a suicide, a physician must file a form listing the precise drugs used to assist a suicide with State authorities. Therefore, the DEA may identify all cases in which federally controlled substances have been used to assist suicide in Oregon in compliance with Oregon law simply by obtaining reports from the Oregon Health Division without ever having to review patient medical records or otherwise investigate doctors.[47] Doctors in Oregon who prescribe controlled substances for pain relief only will have no reason to fear investigation of their use of controlled substances for pain, and should not, therefore, be deterred in any way from prescribing pain relief.

Promoting Palliative Care Through Education and Training

According to the American Medical Association, "the prohibition on physician-assisted suicide provides health care professionals with a tremendous incentive to improve and expand the availability of palliative care."[48] This judgment has been confirmed time and time again, as new State and Federal restrictions on assisted suicide have been followed by significant progress in palliative care and increases in the use of controlled substances for pain control.[49] The American Medical Association has previously testified before this subcommittee, however, that the failure of most States to expressly permit pain management that may unintentionally hasten death has "generated reluctance among physicians to prescribe adequate pain medication."[50] In short, people may be suffering needlessly because of a lack of understanding about the appropriate use of pain medicine in palliative care. H.R. 2260 will do much to correct this grave and unnecessary problem by encourag-

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[47] The DEA has authority to subpoena dispensing records from State authorities. Under 21 U.S.C. § 876 of the CSA, "[i]n any investigation . . . with respect to controlled substances, the Attorney General may . . . require the production of any records (including books, papers, documents, and other tangible things which constitute or contain evidence) which the Attorney General finds relevant or material to the investigation."

[48] Brief of the American Medical Association, *et al.*, as Amicus Curiae in Support of Petitioners at 22, *Vacco* v. *Quill*, 521 U.S. 793 (1997) (No. 95–1858).

[49] See Doerflinger Testimony (citing advances in palliative care in Veterans Administration hospitals after enactment of the Assisted Suicide Funding Restriction Act as well as increased morphine use after enactment of state bans on assisted suicide). The DEA has released its figures on per capita morphine use for the period of January to June 1999. Drug Enforcement Admin., U.S. Dep't of Justice, Statistics on Individual State Consumption of Morphine (on file with Subcomm. on the Constitution of the House Comm. on the Judiciary). Kansas experienced a significant increase in morphine use following the addition of civil penalties to its existing criminal ban on assisted suicide in 1998; previously ranked 35th among states in morphine use, Kansas is now ranked second with 2287 grams per 100,00 population. *Id.* Louisiana was ranked 41st in morphine use in 1994, the year before enactment of its assisted suicide ban; it is now 9th among states in morphine use. *Id.* Tennessee was ranked 16th in morphine use in 1992, the year before it enacted a ban on assisted suicide, and has risen to 8th place among states. *Id.* Empirical evidence, therefore, supports the AMA's claim that clear laws against assisted suicide promote aggressive pain management. Thus, the two purposes of H.R. 2260—to clarify the federal policy against assisted suicide and in favor of pain management—are mutually supportive.

The DEA figures show Oregon with the highest per capita consumption of morphine, at 2332 grams per 100,000 population. *Id.* Two comments are in order with regard to Oregon. First, the DEA figures do not indicate for what the morphine is used. Some assisted suicides may use large doses of morphine (as did one of the 15 cases reported in the Oregon Health Division report), and it is unknown how many unreported cases of assisted suicide occur now that the state has officially sanctioned assisted suicide. Second, the current per capita consumption (2332) is slightly less than per capita consumption during the first half of 1998 (2385)—the period *before* the Attorney General "decriminalized" assisted suicide under the CSA.

[50] *Hearing on Assisted Suicide in the United States Before the Subcomm. on the Constitution of the House Comm. on the Judiciary*, 104th Cong. (April 29, 1996) (statement of Lonnie R. Bristow, M.D., President, American Medical Association).

ing doctors to use controlled substances to relieve pain and suffering and by educating health care professionals and law enforcement personnel about palliative care. One medical expert who testified before the subcommittee stated that, "pain management without this bill is abysmal in the United States . . . [H.R. 2260] provides a much needed service to the dying while protecting vulnerable persons from the real and dangerous effects of the acceptance and practice of assisted suicide/euthanasia as public policy."[51]

In Title I, H.R. 2260 authorizes the Attorney General to carry out educational programs for law enforcement personnel, based on recommendations by the Secretary of Health and Human Services, on the necessary and legitimate use of controlled substances in pain management and palliative care. This provision is designed to encourage law enforcement personnel to defer to medical judgments by health professionals practicing aggressive pain management. In Title II, the bill amends the Public Health Services Act[52] to authorize programs within the Department of Health and Human Services to develop and advance the scientific understanding of palliative care and for education and training in palliative care. Title II provides for the awarding of grants, cooperative agreements, and contracts to health professions schools, hospices, and other public and private entities to develop and implement palliative care education and training programs for health care professionals in palliative care. The decision to award these programs will be made by peer review groups, each of which must include one or more individuals with expertise and experience in palliative care.

HEARINGS

The committee's Subcommittee on the Constitution held a hearing on H.R. 2260 on June 24, 1999. Testimony was received from the following witnesses: Samira Beckwith, President and CEO, Hope Hospice, Past Chairperson for the National Hospice Organization; Ann Jackson, Executive Director and CEO, Oregon Hospice Association; N. Gregory Hamilton, M.D., Physicians for Compassionate Care; David E. Joranson, M.S.S.W., Senior Scientist and Director of The Pain and Policy Studies Group, Comprehensive Cancer Center, The University of Wisconsin Medical Group; Richard Doerflinger, Associate Director for Policy Development, Secretariat for Pro-Life Activities, National Conference of Catholic Bishops; Walter R. Hunter, M.D., Associate National Medical Director, VistaCare Hospice; David Orentlicher, M.D.; J.D., Professor, Indiana University School of Law-Indianapolis Center for Law and Health; and Thomas Marzen, General Counsel, The National Legal Center for the Medically Dependent & Disabled, Inc.

COMMITTEE CONSIDERATION

On July 20, 1999, the Subcommittee on the Constitution met in open session and ordered favorably reported the bill H.R. 2260, without amendment, by voice vote, a quorum being present. On September 14, 1999, the committee met in open session and or-

[51] Hunter Testimony.
[52] 42 U.S.C. § 294 et seq.

dered favorably reported the bill H.R. 2260 without amendment by a recorded vote of 16 to 8, a quorum being present.

VOTE OF THE COMMITTEE

1. An amendment was offered by Mr. Watt to insert language that would authorize the dispensing of a controlled substance for the purpose of causing death or assisting in causing death when in compliance with applicable State, Federal or local laws and to strike language requiring the Attorney General to give no force and effect to State law authorizing or permitting assisted suicide or euthanasia. Mr. Scott requested a division of the question. Section 1 of the amendment was offered by Mr. Watt to insert language establishing exceptions for applicable State, Federal and local laws. The amendment was defeated by a 13–15 rollcallvote.

ROLLCALL NO. 1

	Ayes	Nays	Present
Mr. Sensenbrenner		X	
Mr. McCollum			
Mr. Gekas		X	
Mr. Coble		X	
Mr. Smith (TX)		X	
Mr. Gallegly		X	
Mr. Canady		X	
Mr. Goodlatte		X	
Mr. Chabot		X	
Mr. Barr			
Mr. Jenkins		X	
Mr. Hutchinson		X	
Mr. Pease		X	
Mr. Cannon			
Mr. Rogan			
Mr. Graham		X	
Ms. Bono		X	
Mr. Bachus			
Mr. Scarborough			
Mr. Vitter		X	
Mr. Conyers	X		
Mr. Frank	X		
Mr. Berman	X		
Mr. Boucher			
Mr. Nadler			
Mr. Scott	X		
Mr. Watt	X		
Ms. Lofgren	X		
Ms. Jackson Lee	X		
Ms. Waters	X		
Mr. Meehan	X		
Mr. Delahunt			
Mr. Wexler	X		
Mr. Rothman	X		
Ms. Baldwin	X		
Mr. Weiner	X		
Mr. Hyde, Chairman		X	
Total	13	15	

2. An amendment was offered by Mr. Watt to strike language to give no force or effect to State law authorizing or permitting assisted suicide or euthanasia. The amendment was defeated by a 12–15 rollcall vote.

ROLLCALL NO. 2

	Ayes	Nays	Present
Mr. Sensenbrenner		X	
Mr. McCollum			
Mr. Gekas		X	
Mr. Coble		X	
Mr. Smith (TX)		X	
Mr. Gallegly		X	
Mr. Canady		X	
Mr. Goodlatte		X	
Mr. Chabot		X	
Mr. Barr			
Mr. Jenkins		X	
Mr. Hutchinson		X	
Mr. Pease		X	
Mr. Cannon			
Mr. Rogan			
Mr. Graham		X	
Ms. Bono		X	
Mr. Bachus			
Mr. Scarborough			
Mr. Vitter		X	
Mr. Conyers	X		
Mr. Frank	X		
Mr. Berman	X		
Mr. Boucher			
Mr. Nadler			
Mr. Scott	X		
Mr. Watt	X		
Ms. Lofgren	X		
Ms. Jackson Lee	X		
Ms. Waters	X		
Mr. Meehan	X		
Mr. Delahunt			
Mr. Wexler	X		
Mr. Rothman	X		
Ms. Baldwin	X		
Mr. Weiner			
Mr. Hyde, Chairman		X	
Total	12	15	

3. An amendment was offered by Mr. Scott to strike Section 101 of Title I of the bill regarding reinforcing the existing standard for legitimate use of controlled substances. The amendment was defeated by a 12–16 rollcall vote.

ROLLCALL NO. 3

	Ayes	Nays	Present
Mr. Sensenbrenner			
Mr. McCollum		X	
Mr. Gekas		X	
Mr. Coble		X	
Mr. Smith (TX)		X	
Mr. Gallegly		X	
Mr. Canady		X	
Mr. Goodlatte		X	
Mr. Chabot		X	
Mr. Barr			
Mr. Jenkins		X	
Mr. Hutchinson		X	
Mr. Pease		X	

ROLLCALL NO. 3—Continued

	Ayes	Nays	Present
Mr. Cannon		X	
Mr. Rogan			
Mr. Graham		X	
Ms. Bono		X	
Mr. Bachus			
Mr. Scarborough			
Mr. Vitter		X	
Mr. Conyers	X		
Mr. Frank	X		
Mr. Berman	X		
Mr. Boucher			
Mr. Nadler			
Mr. Scott	X		
Mr. Watt	X		
Ms. Lofgren	X		
Ms. Jackson Lee	X		
Ms. Waters	X		
Mr. Meehan	X		
Mr. Delahunt			
Mr. Wexler	X		
Mr. Rothman	X		
Ms. Baldwin	X		
Mr. Weiner			
Mr. Hyde, Chairman		X	
Total	12	16	

4. An amendment was offered by Mr. Conyers requiring that the government prove beyond a reasonable doubt in a criminal proceeding and by clear and convincing evidence in a civil proceeding that the doctor distributed controlled substances with the intent to cause death. The amendment was defeated by a 9–15 rollcall vote.

ROLLCALL NO. 4

	Ayes	Nays	Present
Mr. Sensenbrenner			
Mr. McCollum			
Mr. Gekas		X	
Mr. Coble		X	
Mr. Smith (TX)		X	
Mr. Gallegly		X	
Mr. Canady		X	
Mr. Goodlatte			
Mr. Chabot		X	
Mr. Barr			
Mr. Jenkins		X	
Mr. Hutchinson		X	
Mr. Pease		X	
Mr. Cannon			
Mr. Rogan		X	
Mr. Graham		X	
Ms. Bono		X	
Mr. Bachus			
Mr. Scarborough		X	
Mr. Vitter		X	
Mr. Conyers	X		
Mr. Frank	X		
Mr. Berman			
Mr. Boucher			
Mr. Nadler			

ROLLCALL NO. 4—Continued

	Ayes	Nays	Present
Mr. Scott	X		
Mr. Watt	X		
Ms. Lofgren	X		
Ms. Jackson Lee	X		
Ms. Waters			
Mr. Meehan			
Mr. Delahunt			
Mr. Wexler	X		
Mr. Rothman	X		
Ms. Baldwin	X		
Mr. Weiner			
Mr. Hyde, Chairman		X	
Total	9	15	

5. An amendment was offered by Mr. Conyers allowing a doctor to assert an affirmative defense that he did not intend to cause death with controlled substances when his intent to cause death had already been proven by the government. The amendment was defeated by a 10–16 rollcall vote.

ROLLCALL NO. 5

	Ayes	Nays	Present
Mr. Sensenbrenner			
Mr. McCollum			
Mr. Gekas			
Mr. Coble		X	
Mr. Smith (TX)		X	
Mr. Gallegly		X	
Mr. Canady		X	
Mr. Goodlatte		X	
Mr. Chabot		X	
Mr. Barr		X	
Mr. Jenkins		X	
Mr. Hutchinson		X	
Mr. Pease			
Mr. Cannon		X	
Mr. Rogan		X	
Mr. Graham		X	
Ms. Bono		X	
Mr. Bachus			
Mr. Scarborough		X	
Mr. Vitter		X	
Mr. Conyers	X		
Mr. Frank			
Mr. Berman	X		
Mr. Boucher			
Mr. Nadler	X		
Mr. Scott	X		
Mr. Watt	X		
Ms. Lofgren	X		
Ms. Jackson Lee	X		
Ms. Waters	X		
Mr. Meehan			
Mr. Delahunt			
Mr. Wexler			
Mr. Rothman			
Ms. Baldwin	X		
Mr. Weiner	X		
Mr. Hyde, Chairman		X	

ROLLCALL NO. 5—Continued

	Ayes	Nays	Present
Total	10	16	

6. An amendment was offered by Ms. Jackson Lee to exempt pre-existing State law from the provisions of the bill. The amendment was defeated by a 9–14 rollcall vote.

ROLLCALL NO. 6

	Ayes	Nays	Present
Mr. Sensenbrenner			
Mr. McCollum			
Mr. Gekas			
Mr. Coble		X	
Mr. Smith (TX)		X	
Mr. Gallegly		X	
Mr. Canady		X	
Mr. Goodlatte		X	
Mr. Chabot			
Mr. Barr			
Mr. Jenkins		X	
Mr. Hutchinson		X	
Mr. Pease			
Mr. Cannon		X	
Mr. Rogan		X	
Mr. Graham		X	
Ms. Bono		X	
Mr. Bachus			
Mr. Scarborough		X	
Mr. Vitter		X	
Mr. Conyers	X		
Mr. Frank			
Mr. Berman	X		
Mr. Boucher			
Mr. Nadler			
Mr. Scott	X		
Mr. Watt	X		
Ms. Lofgren	X		
Ms. Jackson Lee	X		
Ms. Waters	X		
Mr. Meehan			
Mr. Delahunt			
Mr. Wexler			
Mr. Rothman			
Ms. Baldwin	X		
Mr. Weiner	X		
Mr. Hyde, Chairman		X	
Total	9	14	

7. An amendment was offered by Mr. Berman providing that violation of title I shall not result in criminal liability. On unanimous consent Mr. Berman modified his amendment to read at the end of page 2, line 24, add the following: Nothing in this section shall constitute any criminal liability other than that already existing. The amendment was defeated by a 9–16 rollcall vote.

ROLLCALL NO. 7

	Ayes	Nays	Present
Mr. Sensenbrenner			
Mr. McCollum			
Mr. Gekas		X	
Mr. Coble		X	
Mr. Smith (TX)		X	
Mr. Gallegly		X	
Mr. Canady		X	
Mr. Goodlatte		X	
Mr. Chabot		X	
Mr. Barr			
Mr. Jenkins		X	
Mr. Hutchinson		X	
Mr. Pease			
Mr. Cannon		X	
Mr. Rogan		X	
Mr. Graham		X	
Ms. Bono		X	
Mr. Bachus			
Mr. Scarborough		X	
Mr. Vitter		X	
Mr. Conyers	X		
Mr. Frank	X		
Mr. Berman	X		
Mr. Boucher			
Mr. Nadler			
Mr. Scott	X		
Mr. Watt	X		
Ms. Lofgren	X		
Ms. Jackson Lee	X		
Ms. Waters	X		
Mr. Meehan			
Mr. Delahunt			
Mr. Wexler			
Mr. Rothman			
Ms. Baldwin	X		
Mr. Weiner			
Mr. Hyde, Chairman		X	
Total	9	16	

8. Final Passage. The motion to report the bill, H.R. 2260, favorably without amendment to the whole House. The motion was agreed to by a rollcall vote of 16–8.

ROLLCALL NO. 8

	Ayes	Nays	Present
Mr. Sensenbrenner			
Mr. McCollum			
Mr. Gekas	X		
Mr. Coble	X		
Mr. Smith (TX)	X		
Mr. Gallegly	X		
Mr. Canady	X		
Mr. Goodlatte	X		
Mr. Chabot	X		
Mr. Barr			
Mr. Jenkins	X		
Mr. Hutchinson	X		
Mr. Pease			
Mr. Cannon	X		
Mr. Rogan	X		

ROLLCALL NO. 8—Continued

	Ayes	Nays	Present
Mr. Graham	X		
Ms. Bono	X		
Mr. Bachus			
Mr. Scarborough	X		
Mr. Vitter	X		
Mr. Conyers		X	
Mr. Frank		X	
Mr. Berman			
Mr. Boucher			
Mr. Nadler			
Mr. Scott		X	
Mr. Watt		X	
Ms. Lofgren		X	
Ms. Jackson Lee		X	
Ms. Waters		X	
Mr. Meehan			
Mr. Delahunt			
Mr. Wexler			
Mr. Rothman			
Ms. Baldwin		X	
Mr. Weiner			
Mr. Hyde, Chairman	X		
Total	16	8	

COMMITTEE OVERSIGHT FINDINGS

In compliance with clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the committee reports that the findings and recommendations of the committee, based on oversight activities under clause 2(b)(1) of rule X of the Rules of the House of Representatives, are incorporated in the descriptive portions of this report.

COMMITTEE ON GOVERNMENT REFORM FINDINGS

No findings or recommendations of the Committee on Government Reform were received as referred to in clause 3(c)(4) of rule XIII of the Rules of the House of Representatives.

NEW BUDGET AUTHORITY AND TAX EXPENDITURES

Clause 3(c)(2) of House Rule XIII is inapplicable because this legislation does not provide new budgetary authority or increased tax expenditures.

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

In compliance with clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the committee sets forth, with respect to the bill, H.R. 2260, the following estimate and comparison prepared by the Director of the Congressional Budget Office under section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, September 24, 1999.

Hon. HENRY J. HYDE, *Chairman,*
Committee on the Judiciary,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 2260, the Pain Relief Promotion Act of 1999.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contacts are Mark Grabowicz (for effects on spending by the Department of Justice), who can be reached at 226–2860; Cyndi Dudzinski (for costs to the Health Resources and Services Administration), who can be reached at 226–9010; Jeanne De Sa (for costs to the Agency for Health Care Policy and Research), who can be reached at 226–9010; Lisa Cash Driskill (for the state and local impact), who can be reached at 225–3220; and John Harris (for the private-sector impact), who can be reached at 226–2618.

Sincerely,

DAN L. CRIPPEN, *Director.*

H.R. 2260—Pain Relief Promotion Act of 1999.

SUMMARY

H.R. 2260 would increase an existing authorization of appropriations to the Health Resources and Services Administration (HRSA) for the purpose of making grants to public and private entities to educate and train health care professionals in palliative care. The bill also would direct the Agency for Health Care Policy and Research (AHCPR) to develop a program to improve palliative care, and would prohibit the use of controlled substances for assisted suicide or euthanasia, regardless of any state law authorizing such activity.

Assuming appropriation of the necessary amounts, CBO estimates that implementing H.R. 2260 would result in additional discretionary spending of about $24 million over the 2000–2004 period. Enacting this legislation could affect direct spending and receipts, so pay-as-you-go procedures would apply; however, CBO estimates that the amounts involved would be less than $500,000 a year.

H.R. 2260 contains both an intergovernmental and a private-sector mandate as defined in the Unfunded Mandates Reform Act (UMRA). CBO estimates that the bill would result in no costs to state, local, or tribal governments, so the threshold established in UMRA ($50 million in 1996, adjusted annually for inflation) would not be exceeded. CBO also estimates that the costs of the private-sector mandate would fall below the threshold established in UMRA ($100 million in 1996, adjusted for inflation).

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary impact of H.R. 2260 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

By fiscal year, in millions of dollars

	2000	2001	2002	2003	2004
CHANGES IN SPENDING SUBJECT TO APPROPRIATION					
Estimated Authorization Level	7	7	7	2	2
Estimated Outlays	3	6	7	5	3

BASIS OF ESTIMATE

For the purposes of this estimate, CBO assumes that the bill will be enacted by or near the beginning of fiscal year 2000, that the necessary amounts will be provided for each year, and that outlays will follow historical spending rates for these activities.

Spending Subject to Appropriation

The estimated change in spending subject to appropriation has two components: (1) an increase in the existing authorization of HRSA grants for education and training of health care professionals, and (2) a new AHCPR research program aimed at improving the quality of care for terminally ill patients.

The existing HRSA grant program received an appropriation of $21 million for fiscal year 1999. This program is part of a larger HRSA activity which has a current authorization of such sums as necessary through fiscal year 2002. H.R. 2260 would increase the existing target level of $23 million a year (within that "such sums" authorization) by $5 million. The agency would use the additional funds to award grants to public and private entities to develop, implement, and evaluate education and training programs in palliative care.

H.R. 2260 would direct AHCPR to develop a research program to improve palliative care, mainly through the collection and dissemination of guidelines for providing such care. CBO estimates that implementing this provision would cost about $1 million in fiscal year 2000 and $2 million annually thereafter, assuming the appropriation of the necessary amounts. (The agency received an appropriation of $100 million for 1999.)

Direct Spending and Revenues

Persons who violate the bill's provisions regarding the use of controlled substances to assist in suicide could face revocation of their license to prescribe controlled substances. Upon revocation of an individual's license, the Drug Enforcement Administration could seize any such substances in their possession. Thus, enacting H.R. 2260 could lead to the seizure of more assets and their forfeiture to the United States, but we estimate that any such increase would be less than $500,000 annually in value. Proceeds from the sale of any such assets would be deposited as revenues into the Assets Forfeiture Fund of the Department of Justice and spent from that fund, generally in the same year. Thus, the changes in direct spending from the Assets Forfeiture Fund would match any increase in revenues to that fund.

Violators of the bill's provisions also could be subject to criminal fines, so the federal government might collect additional fines if the bill is enacted. Collections of such fines are recorded in the budget as governmental receipts (revenues), which are deposited in the

Crime Victims Fund and spent in subsequent years. CBO expects that any additional receipts and direct spending would be negligible.

PAY-AS-YOU-GO CONSIDERATIONS

The Balanced Budget and Emergency Deficit Control Act sets up pay-as-you-go procedures for legislation affecting direct spending or receipts. Enacting H.R. 2260 could affect both direct spending and receipts, but CBO estimates that any such effects would be less than $500,000 a year.

ESTIMATED IMPACT ON STATE, LOCAL, AND TRIBAL GOVERNMENTS

H.R. 2260 contains an intergovernmental mandate as defined in UMRA, but CBO estimates that complying with the mandate would impose no costs on state, local, or tribal governments, and thus would not exceed the threshold established in that act ($50 million in 1996, adjusted annually for inflation).

In October 1997, an Oregon law that legalized doctor-assisted suicide for terminally ill patients went into effect. Since that time, the interaction of the Federal Controlled Substances Act with that state law has been controversial. As it currently stands, under both Oregon and federal law, it is acceptable for doctors in Oregon to use federally controlled substances for the purposes set forth in state law. H.R. 2260 would direct the Attorney General to give no force and effect to such a state law when determining whether the federal registration of a doctor under the Controlled Substances Act is consistent with the public interest. This would be a preemption of the Oregon "Death with Dignity Act" because it would limit the options available to doctors acting under that state law. Because the state would not be required to take any action, the preemption would have no cost. The bill also would authorize $5 million for education and training in palliative care for health care professionals, many of whom are employed by state and local facilities.

ESTIMATED IMPACT ON THE PRIVATE SECTOR

H.R. 2260 would create a new private-sector mandate for physicians registered to prescribe or administer federally controlled substances by prohibiting the use of such substances in physician-assisted suicides. The bill would require the Drug Enforcement Administration to treat the use of controlled substances for physician-assisted suicide as a violation of the Controlled Substances Act in all states, including those where the practice is permitted by law. Doctors who violate the prohibition would lose their registration, would have to give up their stocks of controlled substances, and could face criminal prosecution. Currently, Oregon is the only state that allows physician-assisted suicide. The number of doctors affected and the costs associated with the mandate would be small.

ESTIMATE PREPARED BY:

Federal Costs: DOJ—Mark Grabowicz (226–2860); HRSA—Cyndi Dudzinski (226–9010); AHCPR—Jeanne De Sa (226–9010)

Impact on State, Local, and Tribal Governments: Lisa Cash Driskill (225–3220)

Impact on the Private Sector: John Harris (226–2618)

ESTIMATE APPROVED BY:

Peter H. Fontaine
Deputy Assistant Director for Budget Analysis

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the committee finds the authority for this legislation in Article 1, section 8, clauses 1, 3 and 18 of the Constitution.

SECTION-BY-SECTION ANALYSIS AND DISCUSSION

Section 101: Reinforcing Existing Standard for Legitimate Use of Controlled Substances:

This section amends the Controlled Substances Act to clarify that doctors and other licensed health care professionals are authorized to dispense, distribute, or administer controlled substances for the legitimate medical purpose of alleviating a patient's pain or discomfort even if the use of these drugs may increase the risk of death. This section also reinforces the current law that the administration, dispensing, or distribution of a controlled substance for the purpose of assisting a suicide is not authorized by the Controlled Substances Act.

This section provides that the Attorney General in implementing the Controlled Substances Act shall not give force or effect to any State law permitting assisted suicide or euthanasia.

This section provides that the provisions of the bill are effective upon enactment with no retroactive effect.

Section 102: Education and Training Programs

This section authorizes the Attorney General to incorporate the recommendations of the Secretary of Health and Human Services to carry out educational and research training programs for law enforcement personnel on the necessary and legitimate use of controlled substances in pain management and palliative care.

TITLE II

Section 201. Activities of Agency for Health Care Policy and Research

This section amends the Public Health Services Act by authorizing a program responsibility for the Agency for Health Care Policy and Research in the Department of Health and Human Services to develop and advance the scientific understanding of palliative care. The Agency is directed to collect and disseminate protocols and evidence-based practices for palliative care with priority for terminally ill patients. This section has a definition of palliative care which is based on the Word Health Organization's definition.

Section 202. Activities of Health Resources and Services Administration

This section amends the Public Health Services Act by authorizing a program for education and training in palliative care in the Health Resources and Services Administration of the Department of Health and Human Services. This section allows the Secretary, in consultation with the Administrator for Health Care Policy and Research to award grants, cooperative agreements and contracts to health professions schools, hospices, and other public and private entities to develop and implement palliative care education and training programs for health care professionals in palliative care.

This section requires the applicant for the award to include three educational and informational components in the program 1) the program must have a component that addresses a means for alleviating pain and discomfort, especially in terminally ill patients, including the use of controlled substances; 2) the program must provide information and education on the applicable law on controlled substances, and 3) the information and education must provide recent findings and developments in the improvement of palliative care. Health professional schools, residency training programs, continuing education, graduate programs in the health professions, hospices, and other sites as determined by the Secretary will be used as program sites.

This section requires the Secretary to evaluate the grant, cooperative agreement or contracted programs.

This section mandates that the Secretary shall include one or more individuals with expertise and experience in palliative care in each peer review group involved in the selection of the palliative care awards.

This section defines palliative care.

This section authorizes an additional $5,000,000 annually for the palliative care award program and authorizes the grant cycle to begin with the fiscal year 2000.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, existing law in which no change is proposed is shown in roman):

CONTROLLED SUBSTANCES ACT

TITLE II—CONTROL AND ENFORCEMENT

* * * * * * *

PART C—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES; PIPERIDINE REPORTING

* * * * * * *

REGISTRATION REQUIREMENTS

SEC. 303. (a) * * *

* * * * * * *

(i)(1) For purposes of this Act and any regulations to implement this Act, alleviating pain or discomfort in the usual course of professional practice is a legitimate medical purpose for the dispensing, distributing, or administering of a controlled substance that is consistent with public health and safety, even if the use of such a substance may increase the risk of death. Nothing in this section authorizes intentionally dispensing, distributing, or administering a controlled substance for the purpose of causing death or assisting another person in causing death.

(2) Notwithstanding any other provision of this Act, in determining whether a registration is consistent with the public interest under this Act, the Attorney General shall give no force and effect to State law authorizing or permitting assisted suicide or euthanasia.

(3) Paragraph (2) applies only to conduct occurring after the date of enactment of this subsection.

* * * * * * *

PART E—ADMINISTRATIVE AND ENFORCEMENT PROVISIONS

* * * * * * *

EDUCATION AND RESEARCH PROGRAMS OF THE ATTORNEY GENERAL

SEC. 502. (a) The Attorney General is authorized to carry out educational and research programs directly related to enforcement of the laws under his jurisdiction concerning drugs or other substances which are or may be subject to control under this title. Such programs may include—

(1) * * *

* * * * * * *

(5) studies or special projects to develop more effective methods to prevent diversion of controlled substances into illegal channels; **[**and**]**

(6) studies or special projects to develop information necessary to carry out his functions under section 201 of this title**[**.**]***; and*

(7) educational and training programs for local, State, and Federal personnel, incorporating recommendations by the Secretary of Health and Human Services, on the necessary and legitimate use of controlled substances in pain management and palliative care, and means by which investigation and enforcement actions by law enforcement personnel may accommodate such use.

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PUBLIC HEALTH SERVICE ACT

* * * * * * *

TITLE VII—HEALTH PROFESSIONS EDUCATION

* * * * * * *

PART D—INTERDISCIPLINARY, COMMUNITY-BASED LINKAGES

* * * * * * *

SEC. 754. PROGRAM FOR EDUCATION AND TRAINING IN PALLIATIVE CARE.

(a) IN GENERAL.—The Secretary, in consultation with the Administrator for Health Care Policy and Research, may make awards of grants, cooperative agreements, and contracts to health professions schools, hospices, and other public and private entities for the development and implementation of programs to provide education and training to health care professionals in palliative care.

(b) PRIORITIES.—In making awards under subsection (a), the Secretary shall give priority to awards for the implementation of programs under such subsection.

(c) CERTAIN TOPICS.—An award may be made under subsection (a) only if the applicant for the award agrees that the program carried out with the award will include information and education on—

(1) means for alleviating pain and discomfort of patients, especially terminally ill patients, including the medically appropriate use of controlled substances;

(2) applicable laws on controlled substances, including laws permitting health care professionals to dispense or administer controlled substances as needed to relieve pain even in cases where such efforts may unintentionally increase the risk of death; and

(3) recent findings, developments, and improvements in the provision of palliative care.

(d) PROGRAM SITES.—Education and training under subsection (a) may be provided at or through health professions schools, residency training programs and other graduate programs in the health professions, entities that provide continuing medical education, hospices, and such other programs or sites as the Secretary determines to be appropriate.

(e) EVALUATION OF PROGRAMS.—The Secretary shall (directly or through grants or contracts) provide for the evaluation of programs implemented under subsection (a) in order to determine the effect of such programs on knowledge and practice regarding palliative care.

(f) PEER REVIEW GROUPS.—In carrying out section 799(f) with respect to this section, the Secretary shall ensure that the membership of each peer review group involved includes one or more individuals with expertise and experience in palliative care.

(g) DEFINITION.—For purposes of this section, the term "palliative care" means the active total care of patients whose prognosis is limited due to progressive, far-advanced disease. The purpose of such care is to alleviate pain and other distressing symptoms and to enhance the quality of life, not to hasten or postpone death.

SEC. [754.] *755.* QUENTIN N. BURDICK PROGRAM FOR RURAL INTERDISCIPLINARY TRAINING.

(a) GRANTS.—The Secretary may make grants or contracts under this section to help entities fund authorized activities under an application approved under subsection (c).

* * * * * * *

SEC. [755.] *756.* ALLIED HEALTH AND OTHER DISCIPLINES.

(a) IN GENERAL.—The Secretary may make grants or contracts under this section to help entities fund activities of the type described in subsection (b).

* * * * * * *

SEC. [756.] *757.* ADVISORY COMMITTEE ON INTERDISCIPLINARY, COMMUNITY-BASED LINKAGES.

(a) ESTABLISHMENT.—The Secretary shall establish an advisory committee to be known as the Advisory Committee on Interdisciplinary, Community-Based Linkages (in this section referred to as the "Advisory Committee").

* * * * * * *

SEC. [757.] *758.* AUTHORIZATION OF APPROPRIATIONS.

(a) IN GENERAL.—There are authorized to be appropriated to carry out this part, $55,600,000 for fiscal year 1998, and such sums as may be necessary for each of the fiscal years 1999 through 2002.

(b) ALLOCATION.—

(1) IN GENERAL.—Of the amounts appropriated under subsection (a) for a fiscal year, the Secretary shall make available—

(A) * * *

* * * * * * *

(C) not less than $22,631,000 for awards of grants and contracts under sections [753, 754, and 755] *753, 754, 755, and 756*.

* * * * * * *

TITLE IX—AGENCY FOR HEALTH CARE POLICY AND RESEARCH

PART A—ESTABLISHMENT AND GENERAL DUTIES

* * * * * * *

SEC. 906. PROGRAM FOR PALLIATIVE CARE RESEARCH AND QUALITY.

(a) IN GENERAL.—The Administrator shall carry out a program to accomplish the following:

(1) Develop and advance scientific understanding of palliative care.

(2) Collect and disseminate protocols and evidence-based practices regarding palliative care, with priority given to pain

management for terminally ill patients, and make such information available to public and private health care programs and providers, health professions schools, and hospices, and to the general public.

(b) DEFINITION.—For purposes of this section, the term "palliative care" means the active total care of patients whose prognosis is limited due to progressive, far-advanced disease. The purpose of such care is to alleviate pain and other distressing symptoms and to enhance the quality of life, not to hasten or postpone death.

* * * * * * *

DISSENTING VIEWS

We strongly oppose H.R. 2260, the "Pain Relief Promotion Act of 1999." This legislation represents an unnecessary intrusion into the sensitive relationship between terminally-ill patients and their physicians and would empower Federal law enforcement agents to second-guess the considered medical judgment of physicians, pharmacists, and patients. Moreover, by threatening medical professionals with long prison sentences and strict liability, this bill would inhibit physicians from aggressively treating pain, limit patient access to palliative care, and make death more painful.

The bill amends the Controlled Substances Act[1] ("CSA"), which sets forth a system of enforcement and penalties for the manufacture and distribution of controlled substances.[2] The bill has the effect of prohibiting physicians and pharmacists from prescribing controlled substances that cause death and subjects them to criminal penalties (i.e., imprisonment and fines) and civil penalties (i.e., revocation of their license to distribute controlled substances) under the Controlled Substances Act.[3] The bill also requires the Attorney General to ignore any State law that permits assisted suicide.[4]

The provision of the bill requiring the Attorney General to ignore State laws permitting assisted suicide would overturn directly the State of Oregon's Death with Dignity Act, which permits physician-assisted suicide under controlled circumstances.[5] In doing so, however, the bill ignores the safeguards in the Oregon law and violates basic principles of federalism.[6] Moreover, H.R. 2260 runs counter to unanimous Supreme Court decisions authorizing and encourag-

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[1] 21 U.S.C. §§ 801–852.

[2] *Id.* Among other things, the Controlled Substances Act ("CSA") first lists the compounds that are regulated as controlled substances, meaning that persons must have permission from the Attorney General to manufacture and distribute them. Physicians and pharmacists seeking to prescribe controlled substances to alleviate pain must apply to the Drug Enforcement Administration ("DEA") for a license to administer them for "legitimate medical purposes."

[3] See *id.* §§ 824, 841.

[4] H.R. 2260 § 101. Other portions of the bill permit the Attorney General to hold educational and training programs for law enforcement personnel on the appropriate use of controlled substances for palliative care. *Id.* § 102. Title II of the bill amends the Public Health Service Act to develop palliative care research programs. *Id.* §§ 201–02.

[5] Oregon's law permits a competent adult, who is a resident of Oregon and has been determined by two physicians to be suffering from a terminal disease, and who has voluntarily expressed his or her wish to die, to make a written request for medication for the purpose of ending his or her life. Numerous procedural safeguards have been built into the Oregon law to ensure that patients cannot end their lives clandestinely with the help of their doctors. For example, two doctors must diagnose the patient as having a terminal disease and as being of sound mind. The patient's request must be in writing and be witnessed by two disinterested people. In addition, only terminally-ill patients are eligible, so people suffering from depression which causes impaired judgment or other mental and physical illnesses will not be able to end their lives with a physician's assistance. Furthermore, Oregon's law creates severe penalties for abuses under the Act.

[6] *Id.* § 101 ("Notwithstanding any other provision of this Act, in determining whether a registration is consistent with the public interest under this Act, the Attorney General shall give no force and effect to State law authorizing or permitting assisted suicide or euthanasia.").

ing the States to engage in meaningful debate and experimentation on the issue of physician-assisted suicide.[7]

It is for these reasons that several groups concerned about pain relief and the quality of medical care either formally oppose or have significant concerns with title I of H.R. 2260. Among them are the Oregon Medical Association;[8] American Alliance of Cancer Pain Initiatives; the American Pain Foundation; the American Pharmaceutical Association; the American Society of Health-System Pharmacists; the American Society of Pain Management Nurses;[9] the American Academy of Family Physicians;[10] the Oregon Hospice Association;[11] the San Francisco Medical Society;[12] the Rhode Island Medical Society;[13] and the Hospice Federation of Massachusetts.[14] Moreover, the U.S. Department of Justice opposed predecessor legislation in the last Congress.[15]

I. H.R. 2260 VIOLATES BASIC PRINCIPLES OF FEDERALISM

Our opposition to this bill is not tantamount to support for physician-assisted suicide; instead, title I of this bill raises serious federalism concerns because it inserts the Federal Government into what traditionally has been a local medical oversight process, the regulation of medical practices. The federalism issue arises because a significant motive of H.R. 2260's sponsors is to nullify an Oregon referendum that permits physician-assisted suicide.[16]

One of the fundamental tenets of federalism is that the States are free to act as independent laboratories of democracy. In this case, after considerable debate, the people of the State of Oregon decided that terminally-ill people should have the ability to control the time and manner of their death, and the nation can now look

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[7] *Vacco* v. *Quill*, 521 U.S. 793 (1997); *Washington* v. *Glucksberg*, 521 U.S. 702 (1997).

[8] Letter from Richard G. Kincade, President, Oregon Medical Ass'n, to the Honorable Ron Wyden (D–OR), U.S. Senator (July 19, 1999) [hereinafter OMA Letter].

[9] Letter from the American Alliance of Cancer Pain Initiatives, the American Pain Foundation, the American Pharmaceutical Ass'n, the American Soc'y of Health-System Pharmacists, and the American Soc'y of Pain Management Nurses to the Honorable Henry J. Hyde, Chair, House Comm. on the Judiciary (July 19, 1999).

[10] Letter from Neil H. Brooks, MD, Chair, Amer. Academy of Family Physicians, to the Honorable Henry J. Hyde, Chair, House Comm. on the Judiciary (Aug. 12, 1999) [hereinafter AAFP Letter].

[11] *Hearing on H.R. 2260, the "Pain Relief Promotion Act of 1999," Before the Subcomm. on the Const. of the House Comm. on the Judiciary*, 106th Cong., 1st Sess. (June 24, 1999) (written statement of Ann Jackson, Executive Director, Oregon Hospice Ass'n) [hereinafter *June 24, 1999 Subcomm. Hearing*].

[12] Letter from William H. Goodson, III, MD, President, San Francisco Medical Soc'y, to the Honorable Nancy Pelosi (D–CA), U.S. Representative (Aug. 20, 1999).

[13] Letter from Steve DeToy, Rhode Island Medical Society, to Member of Congress (Aug. 3, 1999).

[14] Letter from D. Rigney Cunningham, Exec. Dir., Hospice Found. of Mass., to the Honorable Ron Wyden (D–OR), U.S. Senator (Aug. 3, 1999).

[15] Letter from L. Anthony Sutin, Acting Asst. Attorney General, Office of Legislative Aff., U.S. Dept. of Justice, to the Honorable Henry J. Hyde (R–IL), Chair, House Comm. on the Judiciary 1 (Aug. 3, 1998) (letter concerning H.R. 4006, 105th Cong., 2d Sess. (1998)).

[16] *Judiciary Committee to Markup "Pain Relief Promotion Act of 1999" Tuesday*, Press Release of the Honorable Henry J. Hyde, Chair, House Comm. on the Judiciary (Sept. 8, 1999). Most surprising is the majority's wavering stance on the importance of State referenda. The majority appears to believe that State referenda are worthwhile when they do things such as eliminate affirmative action in California and has even introduced legislation to promote the use of referenda, such as H.R. 1252, the "Judiciary Reform Act of 1998." Chairman Hyde said that H.R. 1252 "recognizes that State referenda reflect, more than any other process, the one-person/one-vote system, and seeks to protect a fundamental part of our national foundation." 144 Cong. Rec. H2246 (daily ed. April 23, 1998) (statement of Rep. Hyde). The current legislation seems to constitute a complete about-face from that position.

to Oregon to see how well such a law functions.[17] The Death with Dignity Act has overwhelming support among Oregonians: 65% of Oregon voters and 66% of Oregon physicians are in favor of it.[18]

Ruling in 1997 on the constitutionality of a State of Washington statute that prohibited physician-assisted suicide, the U.S. Supreme Court observed that "[t]hroughout the Nation, Americans are engaged in an earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide. Our holding permits this debate to continue, as it should in a democratic society." [19] While some of the States engaged in the debate have decided to prohibit physician-assisted suicide,[20] Oregon has not. In a blow to federalism, H.R. 2260 would nullify the democratic will of the people of Oregon as expressed through two ballot referenda. This debate should continue in the States, where it belongs. Dr. David Orentlicher, of the Indiana University Center on Law and Health, stated in his testimony before the Constitution Subcommittee:

> Congress and the courts have long recognized the importance of the laboratory of State experimentation on complicated matters of social policy. Because the optimal approach is often not clear, our Federal system encourages States to try different approaches. With local variations, the country can discover the best course of action. . . . In a bold departure from the Supreme Court's guidance, this Act would bring an abrupt end of State experimentation and the accompanying efforts to protect dignity and independence at the end of life.[21]

A side effect of this contravention of federalism is the politicization of medical standards, which currently are decided on a State-by-State basis. In effect, the Federal Government, through the Justice Department and the Drug Enforcement Administration, would come closer to establishing itself as a "national medical board." As the Oregon Medical Association stated:

> If the Department of Justice is authorized to rule whether prescription of pain medications is a "legitimate medical purpose" we can only conclude that it must adopt Federal regulations to determine the standard of medical care, which may directly conflict with State responsibility for standards of practice for end of life care.[22]

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[17] Physicians with the Oregon Health Department have stated that, by 1998, after the law's first full year in effect, only 23 people had requested lethal prescriptions and only 15 of them had used them. Alissa J. Rubin, *Oregon Assisted-Suicide Law at Risk*, L.A. TIMES, Sept. 14, 1999.

[18] See Oregon Death With Dignity Legal Defense and Education Center, *The Oregon Death With Dignity Act and The Drug Enforcement Administration*.

[19] *Washington*, 521 U.S. at 735.

[20] See *Vacco*, 521 U.S. at 805–06 (listing State laws that prohibit physician-assisted suicide).

[21] *June 24, 1999 Subcomm. Hearing* (written statement of David Orentlicher, MD, Director, Center of Law and Health, Indiana Univ. School of Law, at 5).

[22] OMA Letter. Concerns about a "national medical board" are not limited to Oregon—physicians all across the country "remain[] concerned that a law enforcement agency determination of when pain management practices crosses over into assisted suicide would require the Federal Government to begin to define what is appropriate medical practice." AAFP Letter.

II. H.R. 2260 INCLUDES CRIMINAL PENALTIES THAT WOULD DISCOURAGE PHYSICIANS AND PHARMACISTS FROM AGGRESSIVELY TREATING PAIN

We are also concerned that the bill would discourage physicians and pharmacists from aggressively treating pain by subjecting them to criminal penalties.[23] Although the bill does not explicitly reference any criminal provisions, it amends the CSA in a manner that clearly will result in the application of criminal law provisions to physicians and pharmacists for dispensing controlled substances that cause death.

This is because the CSA—the regime that H.R. 2260 amends—operates as a criminal law, and nothing in the bill alters that operation. Current law, in the form of § 841 of the CSA, states, "[e]xcept as authorized by this subchapter, *it shall be unlawful* for any person knowingly or intentionally—(1) to manufacture, distribute, or dispense . . . a controlled substance."[24] The penalties for violation of § 841 include up to life in prison as well as a $1 million fine.[25]

H.R. 2260 amends the CSA to prohibit the dispensing of drugs that result in death by amending § 823 of the CSA to state "[n]othing in this section authorizes intentionally dispensing, distributing, or administering a controlled substance for the purpose of causing death or assisting another person in causing death."[26] Because no provision in H.R. 2260 provides any authority negating the criminal law provisions provided in current law under § 841 of the CSA, it is clear that the same criminal law penalties will apply to persons who dispense drugs which result in death.[27]

Although the majority disputes this point, attorneys and physicians agree that H.R. 2260 would subject professionals to criminal penalties.[28] For instance, the respected law firm of Heller Ehrman White & McAuliffe noted in a legal opinion that "it is glaringly apparent and deeply troubling [that the bill] will subject physicians to *criminal prosecution* with respect to the medically and ethically difficult decision-making process that they must engage in when providing care during the often painful end of life period."[29] Furthermore, Dr. David Orentlicher, of the Center of Law and Health at Indiana University's School of Law, testified that H.R. 2260 is worse than last Congress's bill because, "with this Act, physicians are at risk not merely for revocation of their license to prescribe

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[23] See 21 U.S.C. § 841. While the majority contends that title I of the bill will enable physicians to treat patients experiencing great pain, we believe that this bill will still have a chilling effect on such practices because physicians could be accused of causing death even when they intended only to reduce pain. See discussion *infra* part II.

[24] 21 U.S.C. § 841(a)(1).

[25] *Id.* § 841.

[26] H.R. 2260 § 101.

[27] The Supreme Court has held affirmatively that the Government can use § 841 to criminally prosecute physicians registered under the CSA for misuse of controlled substances. *United States* v. *Moore*, 423 U.S. 122, 124 (1975).

[28] In opposing the bill, the *New York Times* has observed that under H.R. 2260, "doctors would still have reason to worry that they could be investigated and charged with intent to cause death even when no such intent existed." *Flawed Pain-Relief Bill*, N.Y. TIMES, Aug. 14, 1999, at A12 (op-ed). "Critics [of the bill] are particularly concerned about the bill's provision of criminal penalties for physicians found to have intentionally dispensed a narcotic to assist in a suicide. Law enforcement officers, they say, could easily misinterpret large doses of morphine meant to relieve the pain of pervasive cancer." Alissa J. Rubin, *Oregon Assisted-Suicide Law at Risk*, L.A. TIMES, Sept. 14, 1999.

[29] Letter from Nicholas W. van Aelstyn, Heller Ehrman White & McAuliffe, to the Honorable Ron Wyden (D–OR), U.S. Senator (July 21, 1999) (emphasis added).

controlled substances—as called for in last year's Lethal Drug Abuse Prevention Act—they are also subject to jail time."[30]

Criminal penalties will discourage physicians and pharmacists from aggressively treating pain because they will fear prosecution.[31] Richard G. Kincade, the President of the Oregon Medical Association, stated that "[the bill] is an unprecedented expansion of Government power and is subject to significant and varying interpretations, which will place physicians in the position of defending their practice in pain management if a patient dies."[32] This is particularly harmful because physicians already under-medicate patients for fear of being sanctioned under the *current* law.[33] In its June 24, 1999 testimony before the Constitution Subcommittee, the Oregon Hospice Association pointed out that "the climate that already exists in end-of-life care encourages levels of caution which too frequently result in increased pain and suffering for sick and dying people. This proposed bill would only worsen those conditions."[34] The San Francisco Medical Society also noted:

> In an era when a concerted and long-overdue effort is being made to lessen physicians' fears of prescribing appropriate amounts of medications for pain, we do not need to send a frightening and mixed message of increased investigation, criminalization, and politicization of what should be a private matter between patients and their physicians.[35]

Of course, if the majority really wanted to make it clear that H.R. 2260 would not lead to criminal liability, they would have specified as such in the text of the bill. They failed to do so. Moreover, when Rep. Berman (D–CA) offered an amendment at the full Committee markup to specifically provide that the bill's provisions would impose no criminal penalties,[36] the proposal was rejected on a party-line vote.

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[30] *June 24, 1999 Subcomm. Hearing* (written statement of David Orentlicher, MD, Director, Center of Law and Health, Indiana Univ. School of Law, at 2).

[31] We are also concerned that the bill will dissuade physicians from sharing information with pharmacists about the patient's therapy. Pharmacists will not know the reason the drug is being prescribed and will not be subject to liability. H.R. 2260 will thus lessen the communication among health care providers at the very instant when the pharmacist could provide valuable insight on advancements in areas such as pain management therapy.

[32] OMA Letter.

[33] "Even without a Federal criminal statute, studies of therapy for cancer-related pain found that more than half of patients were under-medicated. In a 1986 study of nearly 900 physicians, 86% said most cancer patients were under-treated. Many physicians acknowledged that they feared raising the suspicions of local medical boards or running afoul of State laws." Alissa J. Rubin, *Oregon Assisted-Suicide Law at Risk*, L.A. TIMES, Sept. 14, 1999.

[34] *June 24, 1999 Subcomm. Hearing* (written statement of Ann Jackson, Executive Director, Oregon Hospice Ass'n, at 2).

[35] Letter from William H. Goodson, III, MD, President, San Francisco Medical Soc'y, to the Honorable Nancy Pelosi (D–CA), U.S. Representative (Aug. 20, 1999). See also *June 24, 1999 Subcomm. Hearing* (written statement of David E. Joranson, Pain & Policy Studies Group, Univ. of Wisconsin Comprehensive Cancer Center, at 6–7); *id.* (written statement of David Orentlicher, MD, Director, Center Law and Health, Indiana Univ. School of Law, at 3) ("As several major studies indicate, the reality is that legal concerns already make physicians overly cautious about prescribing the medications necessary to relieve the pain of their patients. Given the seriously disruptive and traumatic nature of criminal prosecutions, this Act will make physicians err even more on the side of caution.").

[36] The amendment stated in relevant part: "Sec. 103 CRIMINAL LIABILITY.—No violation of the provisions of this title shall result in criminal liability."

III. H.R. 2260 APPEARS TO SUBJECT PHYSICIANS AND PHARMACISTS TO STRICT LIABILITY FOR EFFECTIVELY TREATING PAIN

We also object to the strict liability provisions that appear to be created by the bill, which threaten to penalize physicians and pharmacists whose patients died from an intentional dispensation of controlled substances *even if* the death was *not* intended.

The bill would subject physicians to this type of strict liability because of the purpose and operation of the CSA. Under current law, if a person or entity distributes illegal controlled substances, they are subject to automatic sanctions. There is no need for the law to countenance unintentional distributions of illegal drugs such as heroin because professionals should have the knowledge and discretion to avoid any such distribution.

Thus, for good reason the CSA is currently written as a strict liability law for both criminal and civil purposes and contains no intent requirement. For example, with regard to criminal liability, § 841 of the CSA States, "[i]n the case of a violation of subsection (a) of this section involving [a specific quantity of a specific controlled substance], such person shall be sentenced to a term of imprisonment which may not be less than [a specific number of years] and *if death . . . results from the use of such substances*, shall not be less than [term of imprisonment], a fine not to exceed [specific amount], or both."[37] And with regard to the civil liability, § 824 of the CSA provides that the Attorney General can revoke the controlled substance license of any physician who "has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section."[38]

The problem arises in that H.R. 2260 introduces an offense—distribution of controlled substances that leads to death[39]—that is inherently intent based, yet the bill contains no provision that allows the physician or pharmacist to avoid strict or automatic legal responsibility by establishing that they merely intended to relieve pain, even where death inadvertently results, as is often the case in terminal illness situations.

The bill's proponents argue that its introductory language, which States that controlled substances can be used to relieve pain even if the risk of death is increased,[40] would protect doctors whose patients *unintentionally* die from controlled substances. The introductory language is, however, *not* written in an operative manner; it merely states that it is the bill's *purpose* that controlled substances be used to relieve pain even if such substances increase the risk of death. There is no assurance that courts or prosecutors would

[37] 21 U.S.C. § 841(b).

[38] *Id.* § 824(a)(4). In determining what conduct is in the public interest for controlled substances, the Attorney General must consider, among other things, (1) a registrant's compliance with Federal, State, and local laws, and (2) the public health and safety. See *id.* § 823. The statute does not specifically state that using a controlled substance outside of a legitimate medical purpose is inconsistent with the public interest, but courts have upheld Drug Enforcement Administration orders to registrants implying that non-legitimate medical uses of controlled substances would not be within the public interest. See *Harline* v. *DEA*, 148 F.3d 1199 (10th Cir. 1998).

[39] Again, this offense is introduced by virtue of § 101 of H.R. 2260 which provides that "Nothing in this section authorizes intentionally dispensing, distributing, or administering a controlled substance for the purpose of causing death or assisting another person in causing death."

[40] H.R. 2260 § 101.

refer to that language in determining whether to prosecute and/or incarcerate physicians or pharmacists who might dispense controlled substances that *unintentionally* led to death.

The weight of legal authority supports the view that the bill may result in strict liability for physicians and pharmacists. The law firm of Heller Ehrman has stated that the legislation would leave physicians exposed to penalties "even if their subjective intent was to provide palliative care."[41] In addition, the Supreme Court has reaffirmed the view that the CSA operates to provide strict liability.[42]

Although the majority refuses to acknowledge the strict liability implications of the bill, their actions and the bill's legislative history suggest otherwise. Again, if the majority wanted to require that intent be established for a doctor or pharmacist to violate the CSA, they could have done so by stating as much in the text of the bill, but they failed to do so. Moreover, the majority tellingly rejected two amendments offered by Ranking Member Conyers (D–MI) that would have (1) required the Government to prove the *intent of the physician or pharmacist to cause death*,[43] and (2) permitted physicians and pharmacists an affirmative defense to establish that they did not intend to cause death through the distribution of a controlled substance.[44]

IV. H.R. 2260 CONTRAVENES THE PURPOSE OF THE CONTROLLED SUBSTANCES ACT AND IMPOSES ADMINISTRATIVE DIFFICULTIES

This bill is misguided also in the manner in which it attempts to ban physician-assisted suicide and in its creation of administrative difficulties. As discussed earlier, the bill amends the CSA in a specific attempt to regulate medical practice and prohibit the use of controlled substances to cause death. The CSA, however, was *not* intended to regulate medical decision making; it clearly states that it is, instead, a law that addresses drug diversion and trafficking.[45] In opposing predecessor legislation last Congress, the Justice Department recognized this and noted these types of bill "would inevitably divert [DEA] attention away from the core mission of strictly controlling Schedule I drugs and preventing the abuse, diversion of

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[41] Letter from Nicholas W. van Aelstyn, Heller Ehrman White & McAuliffe, to the Honorable Ron Wyden (D–OR), U.S. Senator (July 21, 1999).

[42] *United States* v. *Johnson*, 71 F.3d 539, 542 (6th Cir. 1995) (holding that, to obtain a conviction under the CSA, the Government must prove that (1) the defendant distributed a controlled substance, (2) the defendant acted intentionally or knowingly, and (3) the defendant acted without a legitimate medical purpose and outside the course of professional practice) (citing *United States* v. *Varma*, 691 F.2d 460, 462 (10th Cir. 1982)).

[43] The amendment stated: "(4) In any proceeding governed by the rule set forth in this subsection, the party asserting conduct that is not consistent with public health and safety or not consistent with the public interest must prove beyond a reasonable doubt (in a criminal case) or by clear and convincing evidence (in a civil proceeding) the intent to dispense, distribute, or administer a controlled substance for the purpose of causing death or assisting another person in causing death."

[44] The amendment stated: "(4) AFFIRMATIVE DEFENSE.—It shall be an affirmative defense to a civil or criminal proceeding under this title that a person charged with a violation under this subsection was intending to alleviate pain or discomfort in the usual course of professional practice, including dispensing, distributing, or administering a controlled substance, even if the use of such a substance may have increased the risk of death. Such affirmative defense may be established by a preponderance of the evidence."

[45] 21 U.S.C. §§ 801–801a.

and trafficking in all scheduled drugs."[46] David E. Joranson of the University of Wisconsin's Comprehensive Cancer Center pointed out that, to the extent medical and scientific decisions are made on the Federal level, they should be within the province of the U.S. Department of Health of Human Services, not the U.S. Department of Justice.[47]

Not only does the bill contort the purpose of the CSA, it also would lead to the establishment of a new and burdensome oversight mechanism whereby the DEA would be expected to police every prescription that every healthcare worker, distributor, and manufacturer in the country dispenses. Moreover, the DEA could monitor such activities only by imposing vast new paperwork requirements on all regulated parties or through a network of healthcare workers reporting on each other, the likes of which would be unprecedented and fundamentally destructive to the proper functioning of the practice of medicine. All of this would occur even though the DEA has no expertise whatsoever in medical care.[48]

CONCLUSION

Although some of us do not support the practice of physician-assisted suicide, none of us can support this legislation. This bill overrides Oregon law, which legalized physician-assisted suicide in that State. While there have been instances in our Nation's history where it was appropriate for Federal law to supercede State law in order to fulfill constitutional imperatives, such as the realm of civil rights, this is not one of those occasions. States historically have regulated the medical profession, and the Federal Government has no constitutional authority or imperative to do so now.

Furthermore, we are concerned about the effect this legislation would have on the treatment of pain. If this legislation is enacted, physicians will fear writing prescriptions that could trigger a Federal enforcement process that would ruin their careers and throw them in jail. Consequently, they will be reluctant to prescribe the large doses of narcotics that are often required to treat incapacitating levels of pain. Patients will be left to suffer.

Finally, this legislation will not end the practice of physician-assisted suicide. To the extent that supporters of this bill hope to put an end to physician-assisted suicide, they will be disappointed once the bill is put into practice. Physicians will still be able to use non-controlled substances to assist suicides. Because of the ill effects this legislation will have on the well-being of patients and on the rights of the States, we must dissent.

JOHN CONYERS, Jr.

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[46] Letter from L. Anthony Sutin, Acting Asst. Attorney General, Office of Legislative Aff., U.S. Dept. of Justice, to the Honorable Henry J. Hyde (R–IL), Chair, House Comm. on the Judiciary 1 (Aug. 3, 1998).

[47] *June 24, 1999 Subcomm. Hearing* (written statement of David E. Joranson, Pain & Policy Studies Group, Univ. of Wisconsin Comprehensive Cancer Center, at 2). If Congress does change current law with respect to the legal uses of drugs, it should amend the Federal Food, Drug and Cosmetic Act, which governs the use of drugs for medical and scientific purposes. *Id.* (written statement of David E. Joranson, at 3).

[48] *Id.* (written statement of David Orentlicher, MD, Director, Center of Law and Health, Indiana Univ. School of Law, at 3) ("By empowering officials of the Drug Enforcement Administration and other Federal, State and local law enforcement personnel to prosecute physicians to determine their intent, this Act subjects physicians who care for dying patients to the oversight of police with no expertise in the provision of medical care.").

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